Magana Trial Manager User Manual

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Contents

1 Introduction

The Magana Trial Manager is a SaaS (software as a service) application provided by MaganaMed GmbH, Regensburg. The main application of the software is the electronic capture and storage (EDC; electronic data capture) of clinical study results. The results are collected in electronic case report forms (eCRFs) and stored in an encrypted database.

The software fulfils the requirements of

- GCP (good clinical practice)
- 21 CFR part 11 (Code of federal regulations, USA)
- GDPR (General data protection regulation)

1.1 Modules

Our software is modular – depending on the needs of your studies, the following modules are available:

Multicenter Create multiple study centers/sites and ensure access separation between centers

Participant Survey Allows data collection directly from study participants – on their own devices or at the study site. Can be used for remote visits, ePRO, patient diaries and more.

Query Management Open, answer and close queries in the system

Visit Scheduler Define time windows for visits and automate survey invitations

Randomization Support for list based randomization. Simple randomization, block randomization stratified randomization

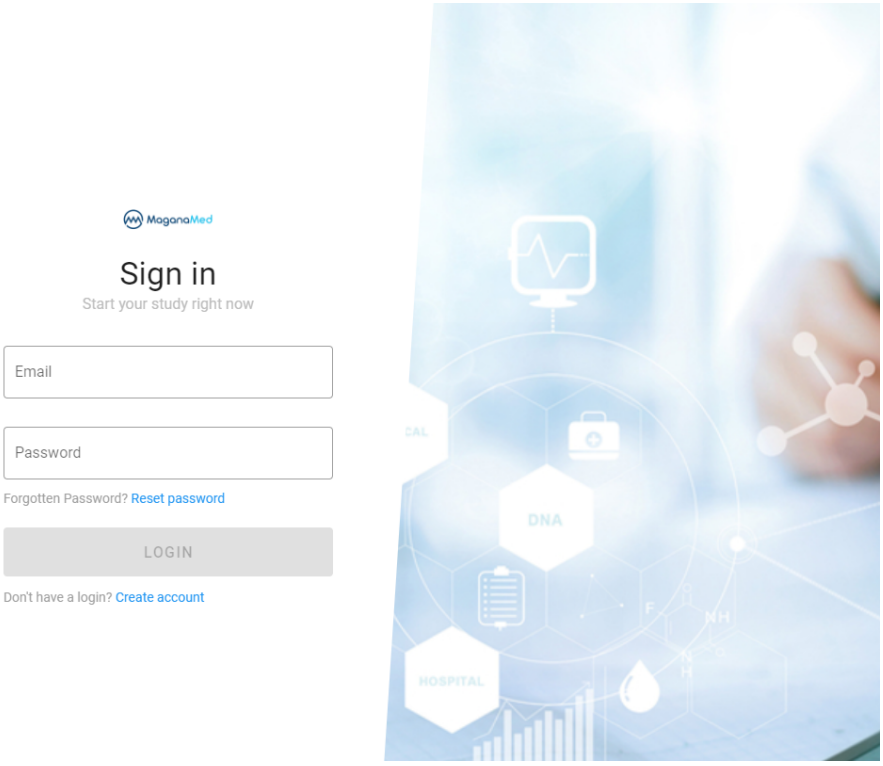
Biosamples Support for barcoding, packaging and life cycle management of biosamples in a trial.

Identity Manager Separate system for storing identifying personal data separately from the clinical data.

API Access Connect external software to Magana Trial Manager for data exchange

1.2 Account Registration and Management

In order to use Magana Trial Manager, you need a user account. You can register yourself at app.magana-trial.com.



Upon registration, you will be asked to give your first and last name, your email-address (= user name) and set a secure password.

Right after registration, you will be directed to a dialog for creating your first study.

Being Invited to a Study

Another way of getting access to the system is by invitation. In that case, an admin user of an existing study sends you an invitation through the system. In that case, the admin has already entered your email address and you will receive an email inviting you to the study. If this is your first invitation to a study in the MaganaMed system, you will be asked to set your password (you will receive the respective link in an email). If you already have an account because you worked in a different study in our system, your email address and password are valid for all studies you have access to.

Strong Passwords

In order to properly protect your account, it is very important to use a strong password:

- At least twelve characters long (>20 would be ideal)
- Include all of the following in your password:
  - upper case letters (A-Z)
  - lower case letters (a-z)
  - numeric digits (0-9)
  - special characters (e.g. `?+=;,!@#$%^&*` etc.)
- Your password must not be a common word that can be found in a dictionary

In order to protect your password

- Never give the password to anyone, including IT admins or MaganaMed staff.
- Never use a password for more than one service.

- When changing your password, make sure to use a completely unrelated password. Never just modify your old password.

Good passwords can be hard to remember and type. Therefore, we highly recommend using a good password manager app. There are many good options – ask your local IT-admin for advice. These programs allow storing all of your passwords in one place while protecting them with encryption. They will assist you when entering these passwords in your web browser and can generate strong passwords for you. I.e. you will not have to memorise most of your passwords or type them manually.

At MaganaMed, we do not have access to your password so we cannot tell you what it is. In case you loose or forget your password, you can reset it yourself using the `reset password` link in the login dialog. MaganaMed Employees will never ask you for your password. If someone does it is most likely a phishing attack.

For additional security, we *strongly* recommend that you also activate two-factor authentication for your account.

Logging In and Out

The Magana Trial Manager can be accessed via www.maganatrial.com. To log in, enter your email address and password. The system will display an icon with your initials in the upper right corner of the screen. That makes it easy to immediately spot who is currently logged in if you are working in an environment where multiple people have access to the system.

To log out, click the "door-icon" in the upper right-hand corner of the screen:

For security reasons, we *strongly* recommend that you lock your local screen/device whenever you are leaving it unattended. After an extended period of inactivity (1 hour) Magana TrialManager will automatically terminate your session for security reasons. However, if you are not planning to continue working in Magana TrialManager, immediately after returning to your device it is advisable to also log out of TrialManager in addition to locking your local screen.

Failed login attempts

Typing good passwords can be error-prone and it is normal that login attempts fail due to typing errors – sometimes a few times in a row. However, multiple failed login attempts for an account may be an indication of a security problem (password guessing or brute-force attack). If our system detects that there were 10 consecutive failed login attempts for an account, it will send you a notification email indicating that these failed logins have happened. If these attempts were made by you, everything is fine. But if you did not try logging in without success, this is a good time, to check, if your password is strong, if you can use password manager to make authentication easier and safer and if you are already using 2-factor authentication to protect your account.

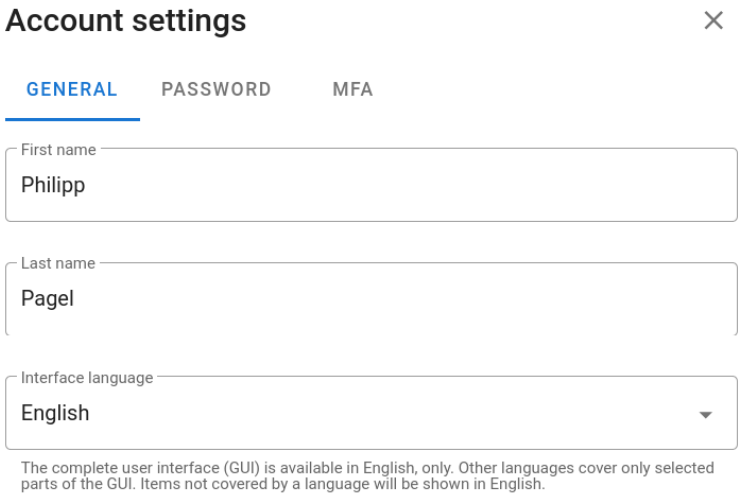
Forgotten passwords

If you ever loose or forget your password, you can recover by clicking on *Reset Password* in the login screen. Enter your email address and click *Send*. You will shortly receive an email with a password reset link that will allow you to set an new password.

Changing your Account Settings

To make changes to your user account settings, click on the account icon with your initials in the upper right corner:

Your account is tied to your email address. But you you can change/correct your first and last name and set you preferred GUI language. Please note that The primary interface language is English – a few other options are available for selected parts of the user interface, only. This mostly applies to parts of the system that are used by site personnel.



In the *Password* tab, you can change your password if needed. Remember to adhere to the rules for good passwords described above.

Two-Factor Authentication (2FA)

In the *MFA* (Multi-Factor-Authentication) tab, you have the option to activate 2FA for your account. This will add an additional layer of security by requiring a second factor (in addition to your password) to log in. Currently, the system supports Time-based one-time passwords (TOTP). In order to use this authentication method you will need a TOTP authenticator app on your smartphone. There are several options available for Android and iOS in the Google-Playstore and Apple App-store, respectively.

After installing the app on your phone, go to the *MFA* tab in your account settings in Magana Trial Manager and scan the QR code with your authenticator app. If the scan was successful the app will display a numeric code that changes every 20 seconds. Enter that code into the fields in Magana Trial manager and click *Enable MFA* to finish the 2FA setup.

Now, every time you log into Magana Trial Manager, you will be asked for username, password and the *TOTP* shown by your authenticator app. Each TOTP is valid for 30 seconds. After that time has elapsed, a new code will be shown. For your convenience, our system will accept the current code as well as the previous one, effectively extending the expiration time to 1 minute and allowing you to use a code that is about to expire. Codes older than that will be rejected.

1.3 Audit Trail

Every change in the software is automatically documented in a GCP-compliant audit trail. The audit trail cannot be changed or deleted. An overview of the last entries of the audit trail is displayed in the Audit section (left navigation panel). It is split into general events (like change in visit structure or permissions) and form changes (e.g. adding or changing a question in a form). Additionally, you can access the audit trail for each individual question by entering the form, clicking on the three dots at the right side of the respective question and then choosing "audit trail". You can only view the audit trail, when you have the required permissions.

1.4 Legal notice

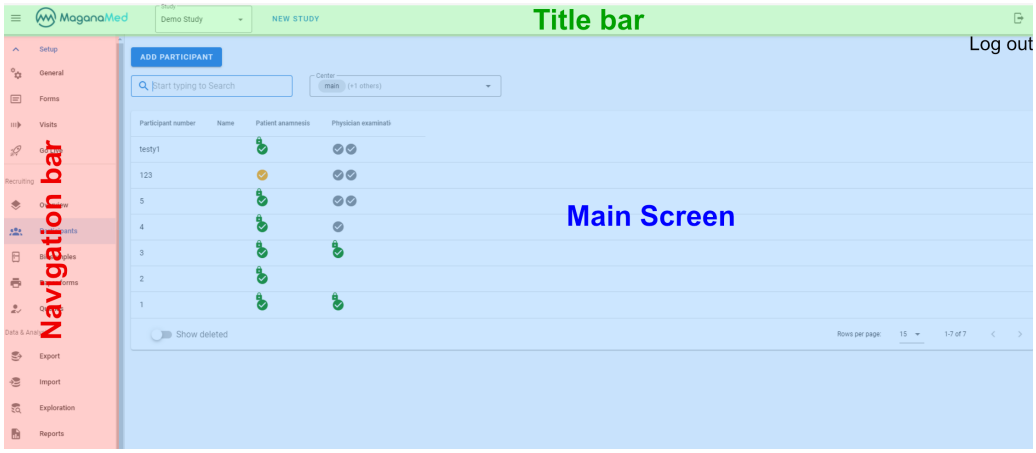
Access to and use of our services is subject to the agreement you enter into with us. Unless otherwise agreed, our services are provided on the basis of the currently valid terms of use. These can be accessed at https://maganamed.com/terms .

This agreement applies regardless of the way in which our services are provided to you. Violation of these terms may result in the temporary or permanent suspension of your account.

1.5 Overview / Structure of the software

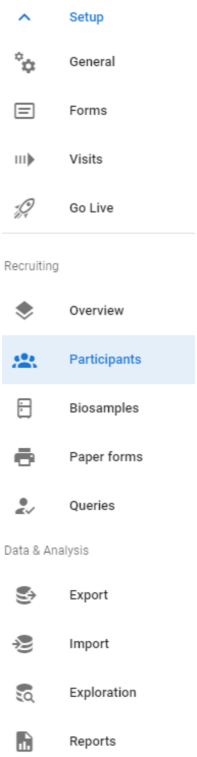
The GUI (graphical user interface) of the Magana Trial Manager puts special attention to intuitive operation. The structure of the GUI and various basic concepts are explained below.

1.6 Structure of the GUI



Navigation bar

On the left side of the screen you can find the navigation bar with all control elements. The navigation bar can be hidden or shown by clicking on the hamburger icon in the upper left corner of the screen.



Title bar

The title bar always shows the MaganaMed logo or, in the case of branded studies, your logo, name of the current study and the option to create a new study. In the top right corner you will find the symbol to log out of the software.

Main screen

All editing steps take place in the main screen.

Submenus

Some menus have additional sub-menus. These are displayed horizontally as tabs under the title bar.

1.7 Phases of the trial

Basically, the Magana Trial Manager does not have a predefined workflow for setting up or conducting your study. Nevertheless, the structure is based on the intuitive life cycle of each study. Therefore, three large sections structure the navigation bar:

Setup

This section contains all settings to set up the entire study (e.g. creation of eforms) as well as the user and center administration. The study can also be switched live or closed here. This menu item is only visible to you if you have the required user permission.

Recruiting

This menu item contains all control elements needed to conduct and control the active study. These include, for example, various overviews of the recruitment status, the processing status of eforms and the query management.

Data Analysis

This menu item contains all tools for working with the received data. This includes, for example, data exploration (to get a first impression of various statistical measures) and data export.

1.8 The user role model

Each user must be assigned a role to define the user's permissions. For example, the role "Monitor" can be authorized to open and close queries and to view study data, but cannot create or change study data.

Roles can be created by users with appropriate permissions. Subsequently, each role can be assigned to any number of users. Each user can only have one role per study center at a time.

For security reasons, roles have to be assigned to all users for each center individually. This ensures that permissions are not inherited unintentionally and allows selective user and role management (e.g. exclusive monitors for different centers).

2 Creating a new study

Depending on whether you had already created a study or whether you had registered with the Magana Trial Manager for the first time, you will find slightly different starting points.

2.1 First study after registration login

After successful registration, you will automatically be prompted to create a new study. To do this, simply assign a study name and select the primary language of your study. Additionally, select all needed modules (functionalities) to conduct your studies. The selection of modules can also be changed later. A detailed description of available modules and corresponding prices can be provided on request (info@maganamed.com)

Then click “Save”.

2.2 Creating additional studies

Click on "New Study" in the title bar next to the name of the current study. On the next screen, assign a study name and select the primary language of your study. Then click "Save".

3 Study configuration

You find the general settings of your study in the navigation bar under setup → general. The setting options include the name of the study, language settings, the logo as well as center and user management. Each setting can be changed at any time - even if the study is already live.

3.1 Basic study settings

The study settings can be accessed via Setup → General → Study.

Remember to click "save" after any change of the study settings.

3.1.1 Changing the name of the study

To change the name of your study, simply click into the field "study name" and change the study as you wish. You can use up to 25 characters for your name (including spaces). Special characters like "*'?)%" can be used, too.

3.1.2 Enabling and disabling Modules

In the field "modules" you can enable or disable purchased modules. Disabled modules won't be visible to any user. Enabled modules will be visible and accessible only to users with respective permissions. If you need access to additional modules currently not included in your contract, please contact our service team (info@maganamed.com) or your account manager.

3.1.3 Adding a logo

Especially bigger studies usually have a logo. To add a logo just click "upload" and select the respective file. The software supports all common image formats.

The logo will appear on surveys and can be added to individual forms.

3.2 Managing languages

The graphics user interface (GUI) of Magana Trial Manager is in English and targets professional users such as study managers, physicians, study nurses, monitors etc. However, sections of the GUI that are primarily used by local site personnel can be translated to other languages and a few options are available already. If you need a language that is not available yet, please contact us.

Users can set their language preference in their account settings (*Account icon* > *Interface language*). All parts of the GUI that have not been translated, will be shown in English, irrespective of user settings.

Independent of the GUI language, you can configure different language settings for the eCRF itself. Our language concept assumes that there are two classes of languages used:

- Primary language
- Additional language(s)

Primary language

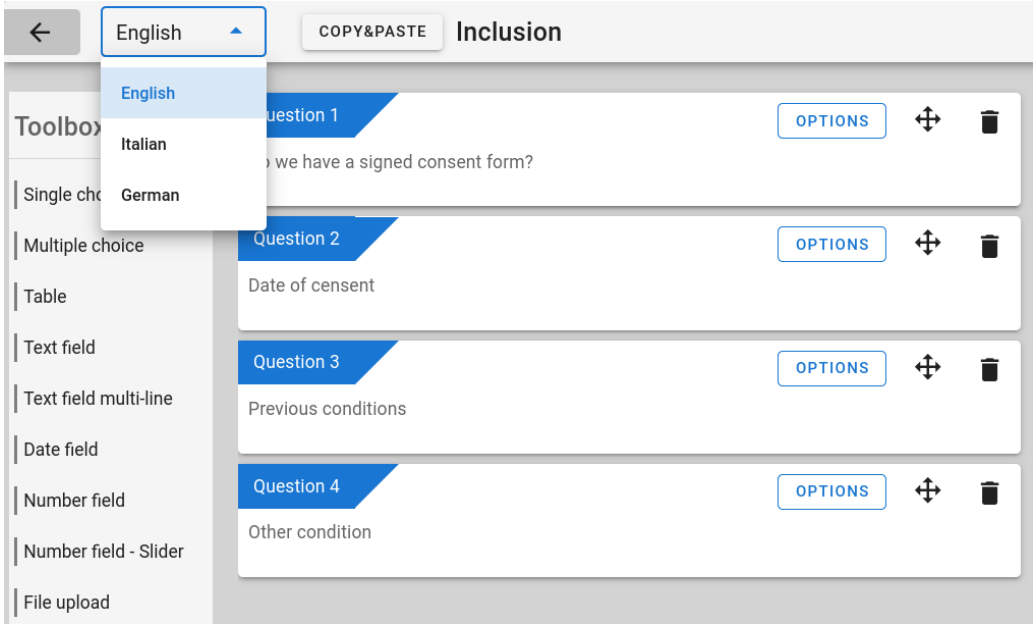
The *primary language* is the language in which you design and implement all forms of a study. Typically, this will be either English or the native language of the leading center/sponsor/etc. Upon creation of a new study, you will be asked to set the primary language. It is possible to change this later (*Settings* > *General* > *Primary language*). However, we strongly recommend to only change this setting before implementing the majority of forms because later change can easily cause confusion.

Additional languages

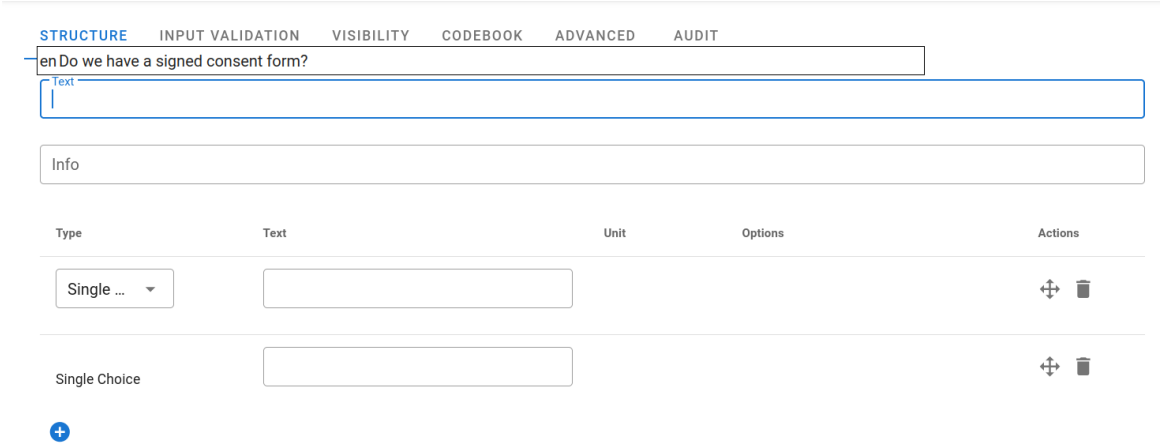
If you want to provide some or all forms of your eCRF in other languages than the primary language, you can do so following these steps:

1. Finalize the CRF design in the primary language
2. Add more languages as needed (*Setup* > *General* > *Additional languages*)
3. Add translations for your forms, form names and visit names.

After setting your additional languages, you can switch between languages in the form editor by selecting the desired language from a drop-down menu:



After switching language, you can add/edit the selected language version. In order to aid the translation process, the system will display the content in the primary language as a tool-tip so the translator does not have to switch back and forth between languages.



It is also possible to translate the names/titles of visits or forms. This can be done under *Setup* > *General* > *Translations*

Setting language preference

For each study site, you can st the preferred language under *Setup* > *General* > *Study Centers* by clicking *Edit* and selecting the preferred *Primary Language* from the drop-down menu. However, site users are not limited to the language set here but can always choose a different language from the drop-down menu at the top of each participant form.

Visit and form titles are shown in the primary or local language following these rules:

- If the user has access to only a single center, the language configured for the center is used. This is a typical case for site users such as study nurses.
- If the user has to access multiple centers, the study primary language is used. This would typically be the case for users in central roles – e.g. study managers, monitors or data managers.
- Survey participants will always see the language that was configured for their center but can switch language the same way as site personnel.

Data structure in multilingual studies

The translations configured as described above, affect the way forms are presented to the users. Internally, the system "knows" that different translations refer to the same data points/fields and stores them accordingly. I.e. entered data is stored in the same database fields irrespective of the form language and the same variable names (as defined in the code book) apply. For numbers, dates, multiple-choice, single-choice etc. this unified storage makes subsequent data analysis very convenient. For text fields (i.e. free input) you need to keep in mind that all input is stored as entered. I.e. you need to deal with translating text input after the fact if needed.

> **Caution**: During validation of your forms, make sure to check that translations really match the original design in the primary language because translation errors or line mix-ups (especially in single/multiple choice questions) will affect the validity of your data!

The obtained clinical data / answers of participants will be stored in the same database independent of the language and thus can be displayed independent of the language selected for data entry.

3.3 Managing study centers

The center management can be accessed via Setup → General → Centers.

3.3.1 Adding or editing a center

To add a center click on the blue button in the top left corner labeled with "add". Enter the name/number/IO of the center and define a prefix for participants from that center. To create the new center, click "save".

For each center, a unique prefix must be defined. This prefix will be part of the participant ID and ensures that IDs are unique throughout the entire study. Prefixes can contain digits, letters and special character. We recommend to end each prefix with an underscore (_) or dash to make them easy to recognize but this is only a recommendation. Some common prefix schemes:

- `B_` for center *Berlin*, `M_` for *Munich* ...
- `DE_M` for *Munich*, `ES_M` for *Madrid*, ...
- `001` for Brussels, `002` for *Rome*, ...
- `1-` for *Athens*, `2-` for *Istanbul*

For each center the decimal separator can be changed. The separator can be a comma (e.g. `1,56` as used in Germany) or dot (e.g. `1.56` as used in the USA, Great Britain, ...).

You can also choose the desired date format for each study center to match the local practice.

Roles of users are not automatically extended to the newly created center but must be assigned separately. This ensures that permissions are not inherited unintentionally and allows selective user and role management (e.g. exclusive monitors for different centers).

To edit the name or prefix of an existing center, click on "edit" on the right side of the center's name. **Caution:** changing the prefix of a center, will *not* affect IDs of any participants already present in the study.

To add a center, the multicenter module must be activated.

3.3.2 Deleting a center

To delete a center click on the three dots on the right side and select delete. The deletion of a center can't be undone. Be careful when deleting centers.

The deletion has no effect on participants and data derived from that center (when the study is live). If the study is still in test mode, deletion of a center will result in the deletion of the respective participants.

A study must have at least one center.

3.4 Configuring participant IDs

The scheme of generating participant IDs / pseudonyms are generated is configurable.

Using predefined schemes of participant ID generation The following predefined schemes are available, by default:

- Center prefix and incremental number without leading zeros (`NYC_123`)
- Center prefix and incremental number with leading zeros (`NYC_00123`)
- Center prefix and four random characters (`NYC_XKFE`)

Creating your own scheme of participant ID generation To create your own scheme, select "custom pattern". Following expressions can be used:

- `$cp` The center prefix which was defined in the center setup.
- `$i` Uses incremental (`1`, `2`, `3`, ...)
- `$i4` Uses Incremental four digits number with leading zeros (`0001`, `0002`, ...). The 4 can be replaced by 2 to 6 to generate two to six digit numbers.
- `$r4` Four random characters (`FZ7L`, `WRDB`, `63K9`, ...). The 4 can be replaced by 2 to 6 to generate two to six random characters.
- `$rl4` Four random letters(`TULD`, `WODP`, `QQPP`, ...). The 4 can be replaced by 2 to 6 to generate two to six random letters.
- `$rd4` Four random digits (`8163`, `2294`, `6294`, ...). The 4 can be replaced by 2 to 6 to generate two to six random letters.

The expressions can be combined to result in your own scheme for participant ID generation. e.g. If the center prefix was defined as `ABC`, the expression `$cp$i3` will result in the following participant IDs: `ABC001`, `ABC002`, `ABC003`, ...

Always include the center prefix in your ID scheme, except for single-center studies.

Manual participant ID modification We strongly recommend to let the system create all participant IDs and not require manual entering or editing of participant IDs, because manual entries are error-prone and the participant ID is a crucial element in correct data identification.

In some cases, however, there are external requirements that force investigators to use external IDs. In order to allow editing participant IDs, select the respective option in *Setup* > *General* > *Study* > *Participant ID*. Site users will now be able to edit the participant ID generated by the system upon participant creation *and* also at a later time. Only users with *add* permission can use this feature. Please make sure to carefully train such users in order to prevent unintended ID changes.

3.5 User management

The user management can be accessed via Setup → General → Users.

3.5.1 Adding a user to your study

You can add an unlimited amount of users to your studies. To grant a user access to your study click on "add user". Type in the person's first and last name plus a valid e-mail address. Click "add" to finalize the invitation. The user will be able to select the study in the title bar from now on. In addition, the user will receive an email with the link to your study.

3.5.2 Assigning a role to a user

Every user of the study must be assigned a role in order to receive permissions. In order to assign a role to a user, click "permissions" on the right side of the user's name. Assign a predefined role to the user and select additional permissions if applicable. Every user must have a separate role for each study center.

3.5.3 Deleting a user

To delete a user, click "delete" on the right side of the user's name. The deletion of a user cannot be undone. Be careful when deleting a user. The deletion of a user will not affect the account of the user but only its access to the selected study. Any data created by this user for this study will also not be affected in any means.

3.6 Roles and permissions

Each user must be assigned a role to define the permissions respectively. Roles can be created by users with appropriate permissions. Subsequently, each role can be assigned to any number of users. Each user can only have one role per study center at a time.

3.6.1 Available permissions

Permissions are set on three different levels:

1. Study permission: access to general settings, eCRF setup, audit trail or the possibility to set a study live.
2. Role permissions: These permissions define for each role what the respective role can view, edit or setup. Each role then can be assigned specifically for each center. So one person can for example have the role "nurse" in center A (with the permission to view, add and edit participants) and the role "monitor" in center B (with the permission to view participants and open/close queries). Note: Each study setting is different. This requires full flexibility in the definition of different roles and permission. Thus, MaganaMed does not predefine roles like "Nurses" or "Monitors", as the respective needed permissions can vary between different studies.
3. Form permissions: It can be defined which role has access to the respective form in a specific visit. One example for an application is, when a lab shall only have access to one particular form in one visit to fill in the lab results.

Study permissions

Study general settings and go live This option enables a user to access all general settings and to set the study live. Having this permission makes the user essentially omnipotent! Accordingly, this should be restricted to a small number of people.

Audit trail access Allows the user to see the top-level audit trail. The detailed audit trail on the question level is accessible to anyone with *view* permission in the respective center.

Forms and visits setup This option enables the respective user to add, edit and delete forms. So it is required for the people who create the forms.

Role permissions

All role permissions apply per center/study site.

View View participant data, forms, queries, audit trail
Add Add new participants to the study
Edit Edit participant forms, add comments and respond to queries
Delete Delete/archive participants
Lock Lock forms for editing
Sign Sign forms
Verify Add verifications to forms – e.g. SDV.
Identity Add, edit and view identifying participant data (like name, date of birth, phone number, email address etc) stored in the *Identity Manager*.
Query Open and close queries. Answering queries just requires *Edit* permission.
View randomization Access the randomization result – i.e. unblind the user with respect to study arm/-group
Randomize Trigger randomization of a participant
Import Import data from csv files into the database
Export Export data and use the data exploration tool
Biosamples Access the biosample module for biosample barcoding, packing and life cycle management. Merely docuenting biosamples only requires *Edit* permission

3.6.2 Defining and deleting roles

To define a new role:

- enter setup → general → users
- click on "manage roles".
- Then click the "+"-symbol
- define the name of the role
- set permissions of the role

To delete an existing role

- enter setup → general → users
- click on "manage roles".
- Then click the "x"-symbol at the right side of the respective role
- confirm deletion

3.6.3 Manage permissions on form level

Sometimes, a role shall only access specific forms of one visit (e.g. the lab only the forms to collect diagnostic lab values). For this, access to forms can be managed on form level.

To assign the access to a form a visit to a specific role:

1. Setup the visit and assign the form to the visit
2. Go to Setup → users
3. Click "Manage form permissions"
4. Assign the target form of the respective visit to one or more roles

3.7 Regulatory settings

In the tab *Regulatory*, you will find a few options that (de-)activate certain features with regulatory significance. By default, all of them are activated as they should be for regular studies under GCP and similar regulations.

If your regulatory situation is different, you can choose to turn off some or all of them.

Please consult with your regulatory expert(s) before deactivating any of the following features and make sure to document the decision appropriately.

Signatures

After go-live, the system will prevent you from making any structural changes to a form once at least one copy has been signed. By removing the checkmark *Before changes can be made in the form designer, all signatures must be invalidated.* you can turn off this behavior: the system will now allow making changes to forms, even if they have been signed.

See also section 7.2.

You can configure the meaning of signatures in your study by editing the *Signature meaning* field.

Reason for change

By default, the system will require users to provide a reason for change when a data point is changed after the respective form has been finished. Study managers can define a list of allowed reasons to choose from here.

It is also possible to disable this feature.

3.8 Surveys (ePRO/eCOA/...) and eDiaries

The survey module supports data entry by the study *participant* instead of site personnel. This mode of data collection is useful for many different situations:

- Remote visits – e.g. quality of life questionnaires filled in at home
- Hybrid visits – i.e. there is a part where data is entered by professionals and another part filled in directly by the participant – e.g. using a tablet or smartphone
- Patient diaries – i.e. the participant collects data repeatedly, e.g. daily

This mode of operation is useful for ePRO (*electronic Patient Reported Outcome*), eCOA (*electronic Clinical Outcome Assessments*), eDiaries and similar applications.

3.8.1 Workflow

There are several different methods of getting a survey invitation to the participant, they serve different needs depending on your specific situation:

- *Ad hoc* email invitation
  A site user enters the participants email address into the address field. The system sends an email, based on a previously defined email template to the specified address. The email address is only used for sending that email but not stored in the database.
  Invitations can be resticted to one specific survey visit or allow access to *all* survey visits of the participant.
  Pro: Simple process
  Con: Needs to be managed manually by site personnel
- External distribution of survey login identifiers
  A list of survey-login identifiers is generated in advance and distributed to study participants outside our system. E.g. by an external email system or even physical mail.
  Survey identifiers (and the respective links) allow participants to access all their survey visits.
  Pro: Easy management of pre-existing cohorts. Allows using pre-established communication channels.
  Con: Requires external management of code distribution.
- Automated, rule based, invitations using the Visit scheduler module
  The *visit scheduler* module allows study managers to define automatic triggers for sending email invitations to participants. These triggers are based on the time since another event, typically a visit. Typical rules are *3 months after the intervention* or *1 year after inclusion*.
  Pro: automated process, no manual action required. Flexible rule definition syntax.
  Con: Site users have no direct control over invitation process.
- Public surveys
  A *public survey* is a configuration that only has one survey URL for all participants. Whenever someone opens that link and starts filling in the form, a new participant is automatically created in the system.
  Pro: Easy URL distribution to large number of potential participants who register themselves for the study.
  Con: Registration is anonymous and you have no control over who tries to enroll. But of course, you can set inclusion criteria for actual recruitment.
- On site survey
  The participant comes to the study site as usual. Site personnel Scans a QR-Code with a mobile device (e.g. a tablet) and is hands it to the participant in order to fill in one or more forms.

Irrespective of the chosen workflow, site users are always able to fill in survey forms themselves as a fall-back option. This is important in case the participant is not capable of or willing to fill it in alone. In that case, a site user can ask the questions and enter the answers on site or during a phone/video call.

Under *Setup* > *General* > *Survey* you can configure man different settings for your surveys.

Study participants do not get regular user accounts and passwords the protection is implemented as a long random string of characters that is unique to the participant (and visit) in order to prevent link guessing attacks. In addition, you should configure the link-lifetime (link expiration) so that they remain valid only for the required period as described below.

Login identifiers

Login identifiers are sequences of 16 random characters resulting in $4.36 \cdot 10^{22}$ (43.6 sextillion) possible links. So if all humans on earth ($8 \cdot 10^9$) were participants in our system, the chance of guessing a valid link would be 1 in $5.45 \cdot 10^{12}$ (one in 5.45 trillion).

These identifiers can be embedded into web links so participants do not need to enter them manually. Alternatively, they can be distributed separately, requiring participants to enter them.

In order to allow the use of login-identifiers, check *Allow login-identifiers* in the *Survey* configuration tab. After that, login identifiers can be generated in two different ways:

1. Interactively in the participant view (*Generate Participant login*) to create a single login identifer, tied to the respective participant.
2. In bulk from the survey setup tab.
   These identifiers are not tied to specific participants. Instead using identifiers from the pre-generated identifier list will automatically create a new participant upon first use.
   So pre-generating identifiers is most useful in situations where you want to send identifiers to a known cohort, outside the system.

To bulk-generate login identifiers, go to *Setup* > *General* > *Survey* and enter the desired number of identifiers into the field next to the study site. Click *Generate* and then *Download* to get the list of all identifiers for that center..

Login identifiers remain valid after the participant has completed the form(s). If you want to prevent the participant from going back and editing the form, later you can lock the form. This can be done automatically by selecting *lock form after completion* when adding the form to a visit (*Visits* > *Context menu of the form* > *Autolock*).

Defining survey URLs

To make your survey accessible to external participants via pre-generated participant login-codes or as a public survey, you must assign a URL (web address) to your survey for each study site. To assign a URL, go to *setup* > *General* > *Survey*. If (and only if) you have selected to allow login-identifiers or made this a public survey, you will see one field for each study site. The fixed part of the URL is shown in all of the fields and cannot be changed, but you can enter your own subdomain(s). If you are trying to use a subdomain that is already in use in another study, an error message will appear.

In most cases, you can use a single subdomain for the entire study. In that case simply enter the same subdomain name in all of the site fields. If however, you want a separate URL for each of your study sites, you can give them separate subdomains.

Public surveys

When the option *public survey* is selected, anyone with the URL can enter the survey. No participant identifier has to be entered. The system will automatically create a new participant for each such access. These participants are anonymous, so if you need to contact these participants later, you need to implement a strategy for making them contact you. In order to make mapping easier, we recommend adding instructions for participants to the survey forms.

Email expiration

By default, survey invitation links never expire. We strongly recommend defining a link expiration time in order to prevent access at much later times. Set an appropriate number of days in the *Email Link Expiration* field. Typically, expiration times of 7, 14 or maybe 30 days are appropriate in most cases.

Email templates and other texts

You should configure a short text that will be shown after participant login and after finishing all forms in the respective text fields.

In order to build a template for email invitation messages, add a new template in *Email Templates*. Define a name (label) for the template, a subject line and text body for the message.

Make sure to always include the phrase `[LINK] xxxx [/LINK]` in all templates – it is the placeholder for the invitation link that the participant is expected to follow.

Email templates accept many common HTML tags for formatting. So you can use markup like bold (`b>xxx</b>`), paragraphs (`<p>xxx</p`) etc. See section Using HTML tags for more examples.

As an advanced option, you can assign a visit and/or a center to this e-mail template. Then this template will be used only for the selected visit/center.

When a survey is sent by e-mail, the selection of the template works like this:

1. a template is searched that matches the participant center and the visit.
2. if none is found, a template is searched which matches the visit and has no center.
3. if none is found, a template is searched that matches the center and does not have a visit.
4. if none is found, the default template is searched, which has neither center nor visit.

Paper/print templates

In case you want to print out survey invitations and give them to the participants on the first visits, you can also define print templates in the same way as described above. Site users can access these pages from the participant view: *Recruiting* > *Participants* > *PARTICIPANT_ID* > *Print*.

In these templates, you can use several placeholders:

- `{{survey.login}}` – the 16 chars login for the participant.
- `{{survey.url}}` – the configured survey url
- `{{survey.qrcode}}` – a qrcode for accessing the survey quickly via smartphone
- `{{participant.identifier}}` – the participant identifier

It is possible to define separate templates for each site/center.

Creating survey visits

To create a survey, configure everything as described above. Then create a visit, select *Diary* in the upper right and add the form(s) for the survey. See also section 6.3.

When a survey is part of a visit that also contains regular elements that are filled in by site personnel, split the visit in two. E.g. *V3 6 month follow-up (participant)* and *V3 6 month follow-up (site)*.

eDiaries

eDiaries work exactly like surveys, but the participant can fill them in multiple times – e.g. daily to create a diary. A new set of survey forms is created each time the participant opens the diary link and clicks the add icon ().

To create a diary, configure everything as described for surveys. Then create a visit, select *Diary* in the upper right and add the form(s) for the diary.

Set-up of visits as eDiary and assignment of forms

To set up a visit as an eDiary enter setup → visit.

- Select "diary" as visit option
- Assign one or more forms to the visit
- Select the three dots at the rights side of each form for further options
  - whether the respective form shall be automatically locked after form completion
  - visibility settings

Note: each form connected to a diary visit can be added multiple times by the participant. The eDiary can be accessed by the participant via the survey log-in code (see section surveys).

3.9 Notifications

To set up notifications enter setup → general → notifications.

Notifications are used to automatically send emails to members of the study team if a predefined event occurs.

3.9.1 Setup of Notifications

- click "add notification
- assign any name to the template under which you want to save it
- Select an notification trigger
  - event (predefined events)
    - participant created
    - query created
    - signature invalidated because of edit
    - verification invalidated because of edit
    - form added to participant
    - form finished
    - form signed
  - computed term (any entry or combination of entries into forms)
    - for programming see MaganaScript
- Select recipients

Note: only persons with access to the current study can be notified

- Select subject of the sent email
- Enter notification text
- CLICK SAVE (notifications are not saved automatically)

Following expressions can be use in the subject and in the text:

- `{{study}}`: name of the study
- `{{center}}`: name of the center of the participant
- `{{participant}}`: pseudonym of the participant
- `{{user.name}}`: name of the user who caused the event
- `{{participantForm.name}}`: name of the form

3.10 Biosample management

To set up biosamples enter setup → general → biosamples.

The Biosample module supports you in the complete workflow related to the samples. From label creation over sample shipping to status tracking, the entire life-cycle of a sample is covered.

- Barcode generation for sample labeling
- Barcoding of secondary containers for shipping
- Documentation of the sample life-cycle from collection to measurement

3.10.1 Setup of Biosamples

A sample set contains all samples which are collected at a given time point at once. This can be only one sample tube or this can consist of various tubes (e.g. Heparin plasma, EDTA plasma, serum).

Create a new sample set type

- click the blue button labeled with "new"
- assign name
- Decide if unregistered samples are accepted.
  (*Allow unregistred biosample IDs*)
- click save

The third point is important: By default, biosample codes will only be accepted by the system if the have been created and registered in the packaging step before use. That protects you against scanning unrelated codes or tubes that have no relation to your study. However, in some situations, you have no control over the codes on sample tubes at the sites. E.g. when they must be provided by the local lab or come from some external software without going through a central packaging step. In those situations, please select the option *Allow unregistred biosample IDs*. Now, no packaging/registration step is required and site users will be able to scan any code into the bio-sample management field.

Create tubes of sample set

- click the blue button labeled with "EDIT" next to the sample set
- Go to the headline "Tubes"
- Type in sample tube type (e.g. EDTA plasma)
- click "add"
- Assign the colour of the tube barcode by typing in the color (e.g. red) in the column "color"
- If a barcode is needed to identify the tube enable the sticker checkbox. If another identifier for the tube is used instead, you can enable the identifier checkbox. This option will allow you to scan or type in any code during the study.
- Click on the blue "SAVE" button to save your changes

Any tube can be moved or deleted by using the symbols next to the respective tube in the column "action".

Create life cycle stages of sample set

- click the blue button labeled with "EDIT" next to the sample set
- Go to the headline "Lifecycle"
- Type in your defined time points, which you want to document during your study (e.g. blood drawn, frozen at -20°C, frozen at -80°C, shipped to lab)
- click "add"
- Click on the blue "SAVE" button to save your changes

Any tube can be moved or deleted by using the symbols next to the respective tube in the column "action".

3.10.2 Generating sample IDs and barcodes

According to your settings (see above) barcodes for sample sets and (if selected) sample tubes can be generated, printed and exported.

Generating sample IDs

To generate IDs for each sample set

- click on the three dots on the right side of the respective sample set
- select "generate IDs".
- Select the needed amount by using the slider.
- Click "generate" to generate the selected number of IDs.

Downloading/exporting sample IDs

To download the generated IDs for each sample set

- click on the three dots on the right side of the respective sample set
- select "download IDs"
- the generated IDs will be downloaded as CSV-file

Generating 2D barcodes from sample IDs

To generate 2D barcodes for each sample set and (if selected) also for each tube,

- click on the three dots on the right side of the respective sample set
- select "print IDs"
- adjust sizes and borders according to your paper template

The big 2D barcode is intended for the bag which contains the set of tubes. Each tube barcode (if selected (see above "Create tubes of sample set") consists of a smaller 2D barcode each, which is additionally labeled with the colour selected for the respective tube.

Once all adjustments have been made, click "print" to print the barcodes.

4 Creating forms

The CRF for your study consists of individual *forms* which are later used in the *visits* of your study. We recommend keeping your forms focussed on specific topics so that they are easy to use in different visits or even other studies in the future.

To create a new form, go to *Setup* → *forms* and then click *new* to add a new form. Enter a name for the form, description and version number are optional. Click *save*. You will automatically enter the form editor.

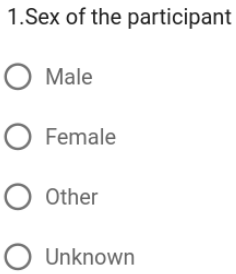
All building blocks of your form are available from the *toolbox* on the left side of the screen. To add an element, drag if from the toolbox and drop it onto the grey workspace next to it. To edit the question, click on *Options*.

4.1 Question types

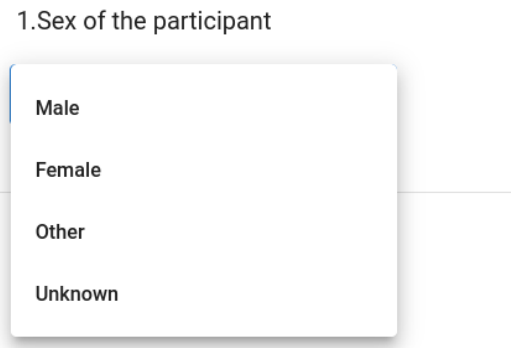
The form designer offers a wide choice of different question types. The most common types are found in the *Data entry* section of the toolbox, specialized types are found in *Special*.

4.1.1 Single choice

Single-choice questions provide several possible choices only one of which can be selected at a time. By default, they are shown as a list of checkboxes:



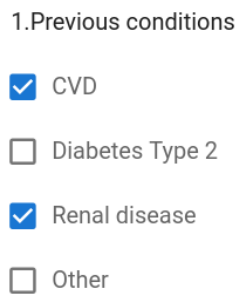
However, their appearance can be changed to a drop-down list (*Advanced* > *display as dropdown*):



You can also change the question-type from *single-choice* to *multiple choice* and back in the form editor.

4.1.2 Multiple choice

Multiple choice questions are similar to single-choice questions, but allow checking as many options as desired:



Like single-choice questions, you can choose to represent them as drop-down menus.

4.1.3 Text field

Text field questions allow entering arbitrary input in a single line of text. While you can set the width of the input field, it will accept more input than the field width can show at a time. The size of the field serves as a visual hint that brief input is expected.

Typical use: short free text answers. E.g. a medical condition, or drugs previously taken.

4.1.4 Text field – multi line

Like the normal text field, a multi-line text field will accept arbitrary amounts of free text input. In contrast to the normal text field, the input field consists of multiple rows and can be re-sized by the user. The size of the field serves as a visual hint that verbose input is expected.

Typical use: Open feedback and similar questions.

4.1.5 Date

The date field expects a well formatted date as its input. Users can either type a valid date into the field or use the graphical input widget to select a date. The input field contains a format hint and will reject ill-formatted input.

Partial dates are not accepted. If you expect that incomplete dates (month and year or only year) will be entered, you can choose one of the following approaches:

1. train your site users to set the unknown part of the date to a specific number – e.g. `2024-08-01` if the day of the month is unknown and `2024-01-01` if only the year is known.
2. Use separate number fields for year, month and day.

4.1.6 Time

The *time* field accepts valid time values. Users can either type in the time in the format `HH:MM` or select a time using the graphical widget that opens when clicking the clock icon.

4.1.7 Number field

As the name suggests, this field type is for numeric input. You can configure the desired number of decimals as well as the visual width of the field and set minimum and maximum allowed input.

4.1.8 Number field – slider

Another incarnation of a numeric field. Instead of typing in a number, you an set a slider visually to indicate a numeric value. This is typically used when the participant is asked to rate something. Also known as a visual analog scale.

4.1.9 Table

Tables allow for compact combinations of checkboxes, numeric fields, text fields etc.

Tables can be useful for groups of closely related items. However, tables were most useful in times when data was collected on paper. In a paper-CRF setting they were compact and quick to fill in.

In an electronic setting they loose some of their appeal as screen space is free and you don't have to worry about the number of pages your CRF will end up having. Still, tables can be useful for some settings. But keep in mind, that tables can become a real hassle on very narrow screens – e.g. on smartphones. So consider who will fill in the form and what kind of device the may be using.

4.1.10 File upload

The file upload field is different from other question types as you cannot type in any data. Instead, it allows uploading a file into the system. Typically, these are images or PDF documents. The system will check the extension of the file and only allow a set of known file types in order to block uploads of e.g. executable files that may pose a security risk to you. Some file types allow previewing the file in the web interface.

Study admins can manage the list of allowed file extensions for their own studies under *Setup* > *General* > *Files*. Please enter the allowed extensions, one per row. Do not include the dot (`.`). The list is pre-filled with a list of popular file types. Study admins can add to the list and remove entries at will.

Caution: Make sure the site users are aware that files uploaded into the eCRF system must not contain identifying information such as names or birth dates. If such data is present in a file it must be anonymized before upload to comply with data protection regulations.

4.1.11 Computed field

Computed fields are very powerful tools. You can carry out calculations in them but also implement little programs for task like computing medical scores, checking inclusion criteria, display data collected from across other forms and visits etc. For a detailed description refer to section MaganaScript.

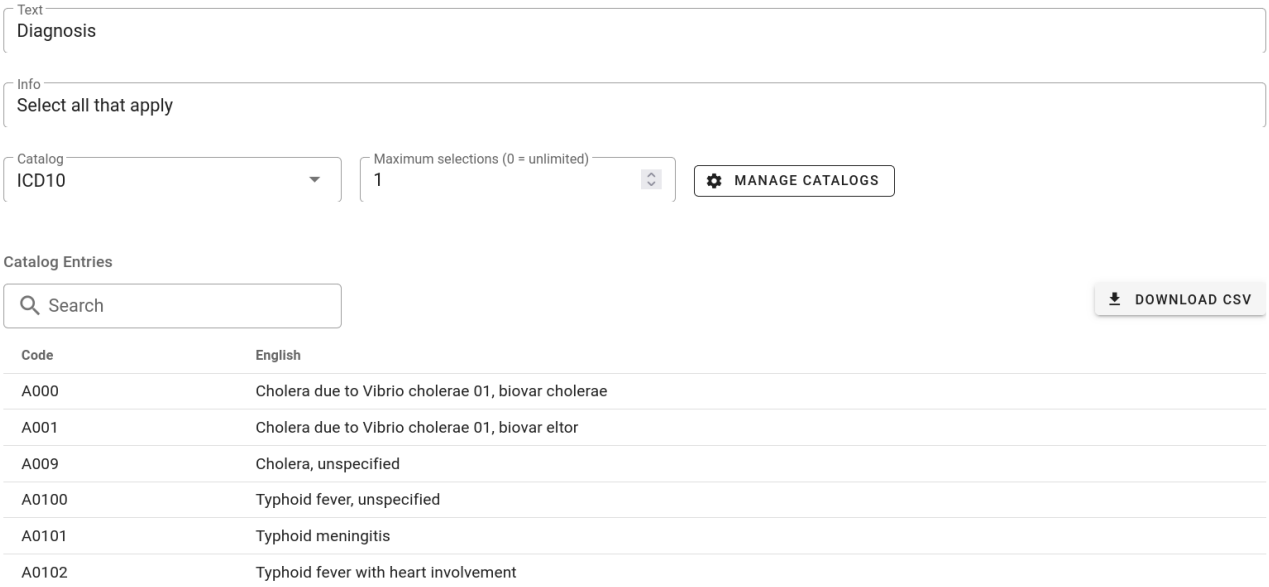
4.1.12 Catalog search

The *catalog* question is similar to *single-choice* and *multiple-choice* questions, but it is intended for handling large numbers of options to choose from, where checkboxes and normal drop-down menus are impractical. Common use cases are choices from catalogs such as ICD-10 or similar.

Setting up a catalog question follows these steps:

1. Add the question to the work area.
2. Fill in the *text* and *info* fields as needed.
3. Add a catalog file (unless it is already available).
    - Click *Manage Catalogs*.
    - Enter a name for the catalog you are adding.
    - Upload a csv file that contains the catalog (see below for format).
4. Select the catalog from the *Catalog* drop-down menu.

As catalogs can be of substantial size, you can reuse them in multiple different locations without needing a separate copy for each question. Once set up, you will see a preview of the first couple of entries of the catalog.



If you want the question to behave like a *single-choice* question, i.e. only allow one option to be selected, set the *Maximum selections* field to *1*. For multiple-choice behaviour set it to *0* or the maximum number of selections you want to allow.

Catalog files must be uploaded in CSV format using a semicolon (;) as a delimiter. At least two columns are required: *code* and the primary language, typically *English*. If you want translations for any additional languages in your study, you need to supply additional columns. The first row of the file is the header that contains the column names. E.g.:

```
code;English
A000;Cholera due to Vibrio cholerae 01, biovar cholerae
A001;Cholera due to Vibrio cholerae 01, biovar eltor
A009;Cholera, unspecified
A0100;Typhoid fever, unspecified
A0101;Typhoid meningitis
A0102;Typhoid fever with heart involvement
```

```
A0103;Typhoid pneumonia
A0104;Typhoid arthritis
A0105;Typhoid osteomyelitis
[...]
```

Or in case of *German* as the primary language using a different coding scheme:

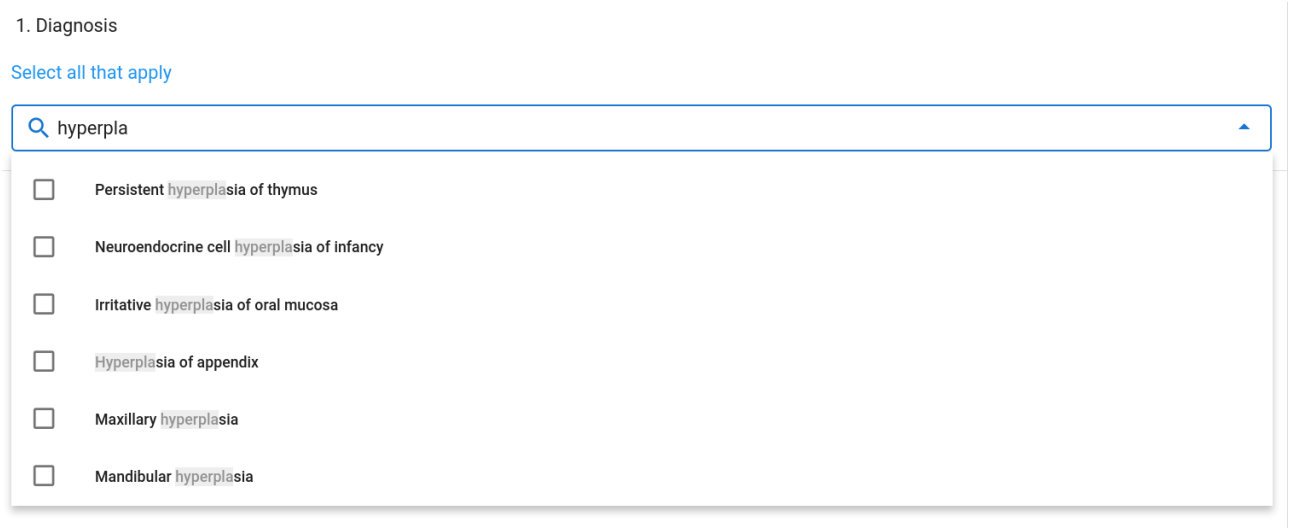
```
code;German
"90016";"A00.0 Cholera durch Vibrio cholerae O:1, Biovar cholerae"
"90017";"A00.1 Cholera durch Vibrio cholerae O:1, Biovar eltor"
"13614";"A00.9 Cholera"
"66377";"A01.0 Abdomentyphus"
"117530";"A01.0 Abdominaltyphus"
"22465";"A01.0 Bauchtyphus"
```

The *code* column *must be unique* and will be used for variable coding in the data export, the language columns contain the searchable clear text that will be shown in the selection.

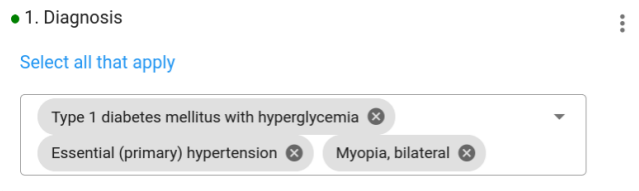
If you do not supply a column for a language, the system shows the text of the primary language, instead.

Usage

Upon clicking into the data entry field, a list showing the first options opens. As soon as you start typing, the choice shown will be limited to entries that match the string entered. Click on an option to select it.

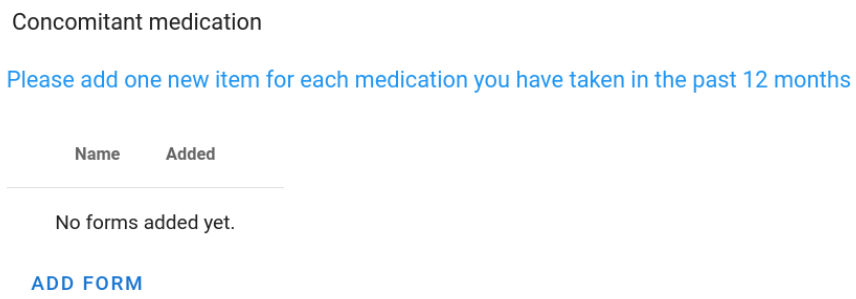


If setup to accept more than one selection, you can add multiple selections:

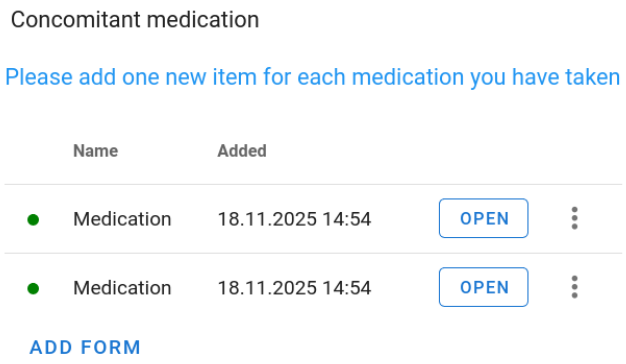


4.1.13 Nested form

A *Nested form* allows you to call another form from within your current form. The use case for a nested form is when you want to potentially get multiple data sets for an entity. E.g. medication. In that case, create a brief *Medication* form that contains all information on *one* medication. Then create a nested form in an appropriate place. Site users can now add as many medication items as needed inside an existing form.



And after adding a few items:



The workflow is in analogy to having addable forms in a visit.

4.1.14 Image map

This field type supports interactive images with defined active areas (eg. parts of the body, states in a country, etc.). The participant can click and select one (single choice) or more (multiple choice) areas of an svg-image.

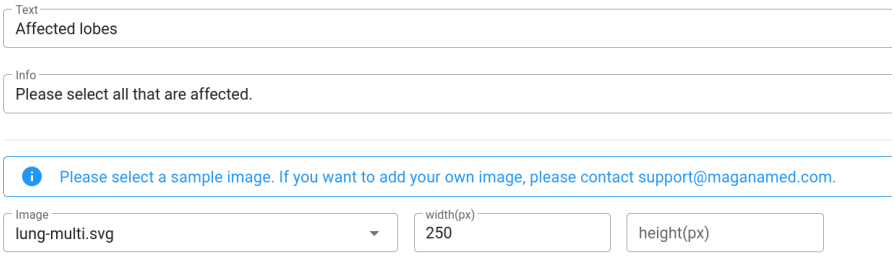
Importable images require some manual setup. The resulting files are in *SVG* format and contain the image, a path definition of active (selectable areas) and matching labels that are imported into the codebook. In order to use your own images with this question type, please get in touch with MaganaMed support.

Once you have such a prepared image, you can setup the question as follows:

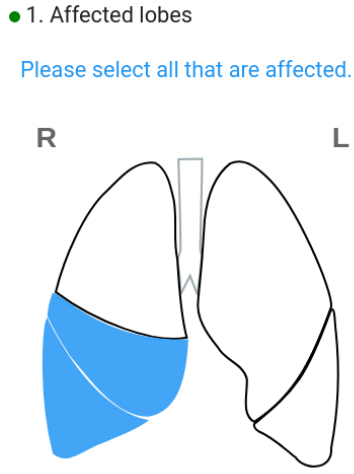
1. Upload your prepared image to the general file area (*Extras* > *Files* > *Upload*)
2. Place an *image map* question on the work area of the form designer
3. Open the question and fill in *text* and *info* fields
4. Select your image from the *Image* menu.
5. Enter the desired image *width* and/or *height*. Providing only one of these sizes will preserve the aspect ratio of the original image.

The system will automatically extract the variable name and coding from the SVG file and fill in the codebook. For your convenience, the system provides two example images (`lung-single.svg` and `lung.multi.svg`) that represent an image map of pulmonary lobes.

Example



Depending on the setup of your image, it will behave like a *single-choice* or *multiple-choice* question. This is what it looks like after selecting two lobes in the right lung:



4.2 Structural/layout elements

4.2.1 Headline

You can add as many headings and sub-headings into your form as you like. That way, users get more guidance on what a form or section is really about. However, if you find yourself adding lots of headlines to a form, it may be time to split a very long form into two (or more) for better modularity.

4.2.2 Info text / image

The info text element can be used to add any free text to your form. That could be a warm welcome to the site personnel, instructions how to fill in a form or just about any additional information that is not immediately linked to a single question.

In addition, you can use this field to add images to your form – e.g. a sponsor logo, a study logo or any kind of supplementary images that make your form easier to use.

4.2.3 Item numbering

By default, all questions are numbered sequentially. You can turn off automatic numbering by setting the *numbering option* in the form's context menu to *none*.

4.2.4 Edit a question

To edit a question, click on *Open* in that question.

Typically, a question has a question *text*, and some optional information (*info*). Many question types also have a *label* field for a short description of the value expected.

4.2.5 Reordering questions

To change the order of questions in a form, grab a question by the *cross symbol* on the right hand side of the respective question and drag it to the desired location.

4.2.6 Deleting questions

To delete a question, click on the bin symbol on the right side of the respective question.

4.3 Copy & paste of questions and forms

You can copy/cut & paste several questions at a time within the same form or even transfer it to another study. To copy or cut one or several questions:

- activate the "copy/paste" function by clicking *copy&paste* in the title bar.
- Choose either *Copy* or *Cut* depending on what you intend.
- Select any number of questions by clicking on them.
- For pasting, go to the position in the form you want the selection to be inserted at and click the *paste* button in that position. The pasting position doesn't need to be in the same form or even the same study.

4.4 Using HTML tags

In the *Text* and *Info* fields of a question, you can use basic html tags for formatting. The same is possible in the response of computed fields.

- Bold text
  `<b>bold text</b>`
- Italics
  `<i>text in italics</i>`
- Colored text
  `<span style="color:red">red text</span>`
- superscript (x^2)
  `x<sup>2</sup>`
- subscipt
  `x<sub>i</sub>`
- Link to external resource
  `<a href="https://foobar.de/foo-score.html">Foo-Score</a>`

- Embedding an image
  `<img src="https://foobar.de/images/nice-picture.jpg">`
  Images can be stored in the file area of the software and then liked to like this.
- Bullet list

```
<ul>
    <li> First </li>
    <li> Second </li>
    <li> Third </li>
</ul>
```

- Numbered list

```
<ol>
    <li> First </li>
    <li> Second </li>
    <li> Third </li>
</ol>
```

- Tables

```
<table>
    <tr>
        <td>Item</td>
        <td>Description</td>
    </tr>
    <tr>
        <td>Foo</td>
        <td>A foo item</td>
    </tr>
    <tr>
        <td>Bar</td>
        <td>A bar item</td>
    </tr>
</table>
```

We recommend sticking to simple tags, depending on your knowledge of HTML. However, more advanced things are possible such as embedding external media content (videos) with `iframes`.

Warning: Linking to or embedding external content can cause risks! Therefore, Magana Trial Manager will only allow content from a list of trusted media sources such as Youtube and Vimeo. While this prevents the majority of risks, we strongly recommend to only embed content that is under your full control (i.e. you control the account providing the media) and/or is provided by a trusted source such as medical agencies and associations. In any case, check the content of your link or iframe before including it and re-check on a regular basis in order to detect changes to that content, even if you trust the source.

4.5 Form Preview

You can check the appearance of your forms on different devices. To select the respective preview click on "view type" at the right side of the title bar. You have following options of preview:

- smartphone
- tablet
- laptop

- PDF (annotated PDF)

After adding/editing/deleting a question, please click reload to refresh the preview.

To enable/disable the preview, click "View type".

The annotated PDF will contain all questions plus optionally input validations, visibility rules, aliases and encodings. To download the form as pdf file, click the download button in the preview window.

4.6 Multi-language studies

Once your CRF is completed in your primary language, you can translate your forms into additional languages. See section Managing languages for details.

4.7 Structure

In the *Structure* tab you can define the core of the question or element. This is the default tab when editing a question (see Question and element types).

Depending on the question/element type you can set

- *Text* (Question text)
- *Info* (additional commen sor instructions)
- *Label* (short description of data to be entered)
- *Unit*
- Selectable answers (single- and multiple-choice)
- Numeric field length, decimal places and min/max values
- ...

4.8 Input validation

Input validation contains a set of functions to check entered data and configure mandatory questions.

4.8.1 Mandatory questions

You can set a question as *mandatory* (*required question*). If this option is selected, The *finish* button at the end of the form will be greyed out and non-functional until all mandatory questions of the form have been answered. As described below, you can define rules that will trigger warnings or error messages. If the action type is set to *Error*, the system will reject the input. *Warning* will show a message but still accept the input.

Input validation is frequently used with numeric fields to define lower and upper limits that are acceptable and/or warn about extreme values that may not be correct but can also be useful for other question types. If you want more control over the checks and/or need custom messages, you can define input validation rules instead of simple numeric limits.

4.8.2 Standard rules

Standard rules can be defined by selecting criteria from a drop-down menu and entering limit values. They are available for number questions.

You can define as many rules as you like. They will be evaluated independently and you can assign individual levels (error or warning) and messages.

4.8.3 Custom rules

Custom validation rules are written as MaganaScript expressions. The validation rule triggers an error or warning if it evaluates to `true`.

The underlying mechanism of custom validations is to define an *Alias* for all items required in the validation rule and then writing an *expression* that evaluates the items somehow. If the rule evaluates to *True*, the rule is triggered – i.e. the message will be shown. This allows for rules to not only use the current data, but to also make us of data from to other questions, forms or visits in the comparison. For the sake of simplicity, we will assume, that the alias for *this* data point has been assigned an alias called `$this`.

String input validation

Text fields are notoriously hard to check, as users can enter anything. However, using computed expressions, you can easily evaluate the input. E.g.:

Reject if the input contains the string *Dog*:

```
regex_test($this, /.*Dog.*/)
```

Reject if the input does not contain the string *Cat*

```
! regex_test($this, /.*Cat.*/)
```

Reject if the input does not start with the string *Foo*

```
! regex_test($this, /^Foo.*/)
```

Numeric input validation

While standard rules are typically sufficient for numbers, there are cases, where custom rules are needed. E.g.

Reject if the input is even:

```
$this % 2
```

Reject if number can be divided by 3:

```
$this % 3
```

Reject if number is larger than it was in visit `v0`:

```
$this > $v0.this
```

Reject if number is larger than square root of another number field in visit `v0`:

```
$this > sqrt($v0.that)
```

Reject if number is one of a few specific values

```
$this == 12 || $this == 21 || $this == 78
```

Single and Multiple choice validation

Validation rules for single and multiple choice questions only make sense in very special cases, because you are in control of the allowed answers to begin with. However, it can be useful when some options become invalid in specific circumstances.

Let's assume we have the following two questions:

- Single-Choice: *Sex* (`$sex`):
  - male (`0`)
  - female (`1`)
- Multiple Choice: *Diagnostic procedures in the past 12 months?*
  - Chest X-ray (`$chest_xray`)
  - Mammography (`$mammography`)
  - PAP smear (`$pap`)
  - Prostate exam (`$prostate_exam`)
  - Spirometry (`$spiro`)

Obviously some of the options are sex specific. So we can define the following custom validation rules:

```
$mammography && $sex == 0     // error: Mammography not possible for a man
$pap && $sex == 0             // error: PAP smear not possible in a male
$prostate_exam && $sex == 1   // error: Prostate exam for a woman not plausible
```

Date validation

As for normal computed fields, you can use our date functions to test if a date is in a certain range. E.g. to reject a visit date if it is within 90 days of another visit date.

```
date_diff($visit_date, $v0.visit_date, "days") < 90
```

4.9 Visibility

Here you can define conditions that mus be fulfilled in order for the question to be shown. Simple rules can be defined from the drop-down menu.

This feature can be useful in many situations – e.g. * After a multiple choice question with an *other* option – just add a text question *Other – please explain* after the question and activate it if *other* is selected. * Only show question about pregnancy f the participant is female. * Hide questions on a certain side effect if it has actually occurred.

You can define more than one condition and select if the question should be shown as soon as one of them is met or if all of them must be fulfilled.

If you need more complex conditions, you can enable *Advanced mode* in which you program the condition using the same syntax as in computed fields.

4.10 Codebook

In this tab, you can define the variable name and coding for your question. These variable names and codings will be used in the data export files. If no variable name is defined, the export data will contain the raw question text which is suboptimal for subsequent data analysis.

Variable names must be *unique* across the *entire study*. Some variable names are used by internal system functions and thus reserved:

- `participant_identifier`
- `center_name`
- `visit_name`
- `created_at`
- `started_at`
- `finished_at`
- `form_index`
- `diary_date`

Never use a reserved variable name for your data.

4.10.1 Rules for variable names

Valid variable names may contain letters, digits and the underscore (_). They must start with a letter (not digit or _). Good variable names are brief, descriptive and in English. Ideally, they follow a common naming scheme and/or are taken from a standard list of names for common items.

4.10.2 Variable coding

Categorical variables that represent answers to single-choice questions require a coding scheme. I.e. a mapping from the natural language description of the respective option to a standardized value to be used when checked. Using numerical coding is very popular, but you can use text values if you prefer.

Typical coding examples for single-choice:

Question:

Do you take any medication?

- Yes
- No

Variable name: `medication`

Coding:

```
"yes" : 1
"no"  : 0
```

Or:

```
"yes" : true
"no"  : false
```

Question:

What is your favorite color?

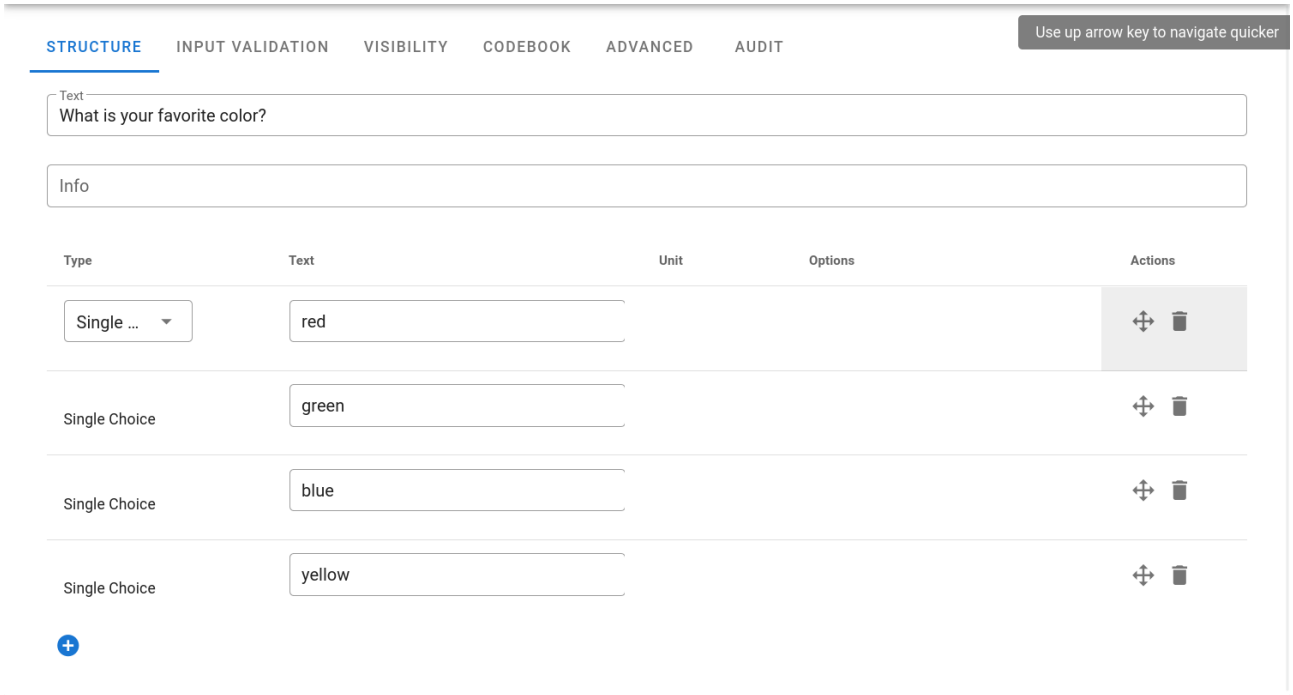
- red
- green
- blue
- yellow

Variable name: `fav_color`

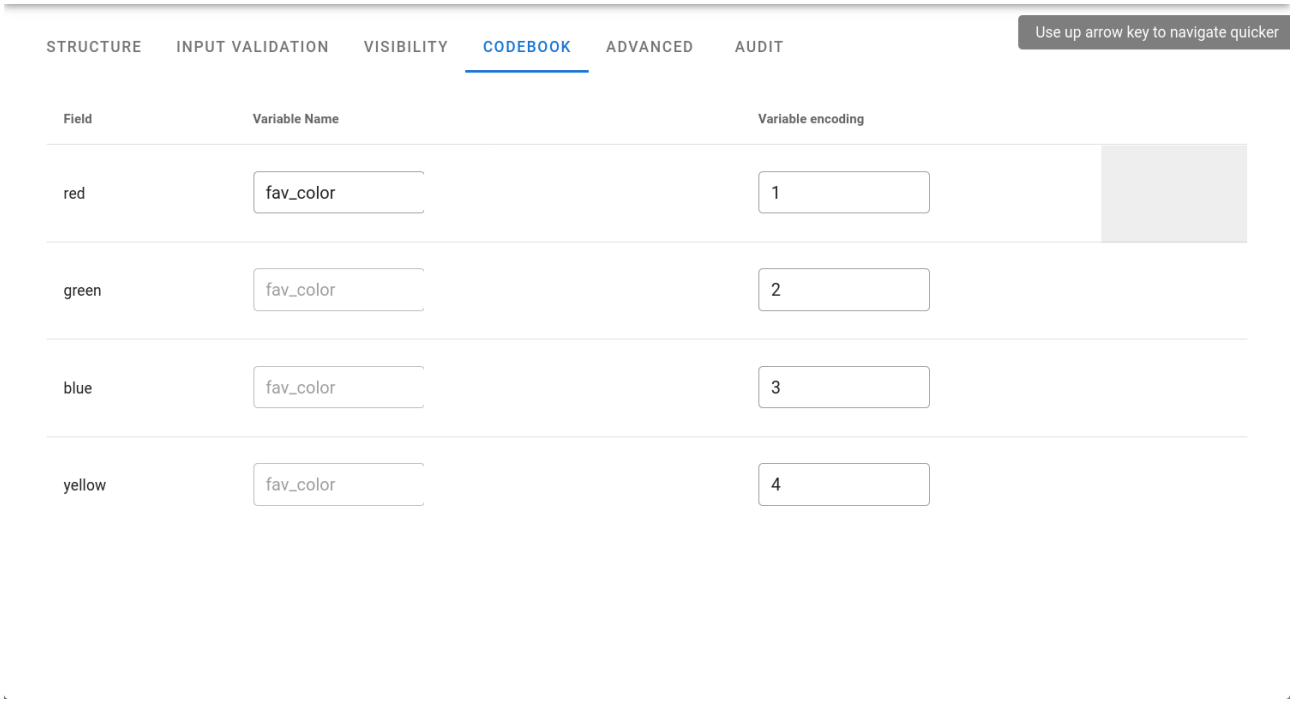
Coding:

```
"red"   : 1
"green" : 2
"blue"  : 3
"yellow": 4
```

The question would be set up like this:



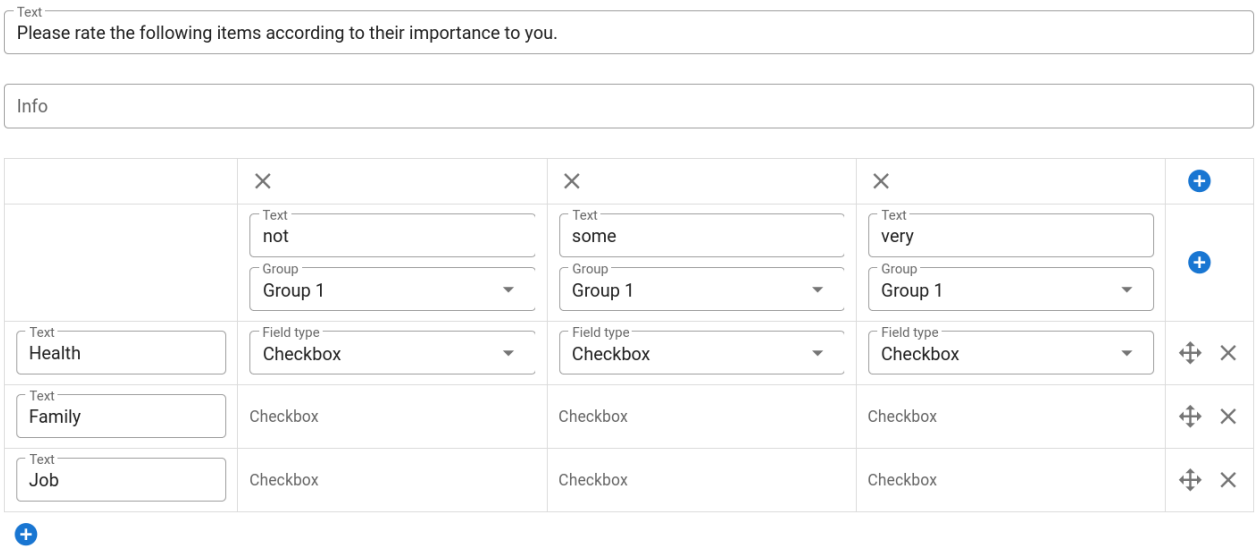
And the corresponding codebook tab looks like that:



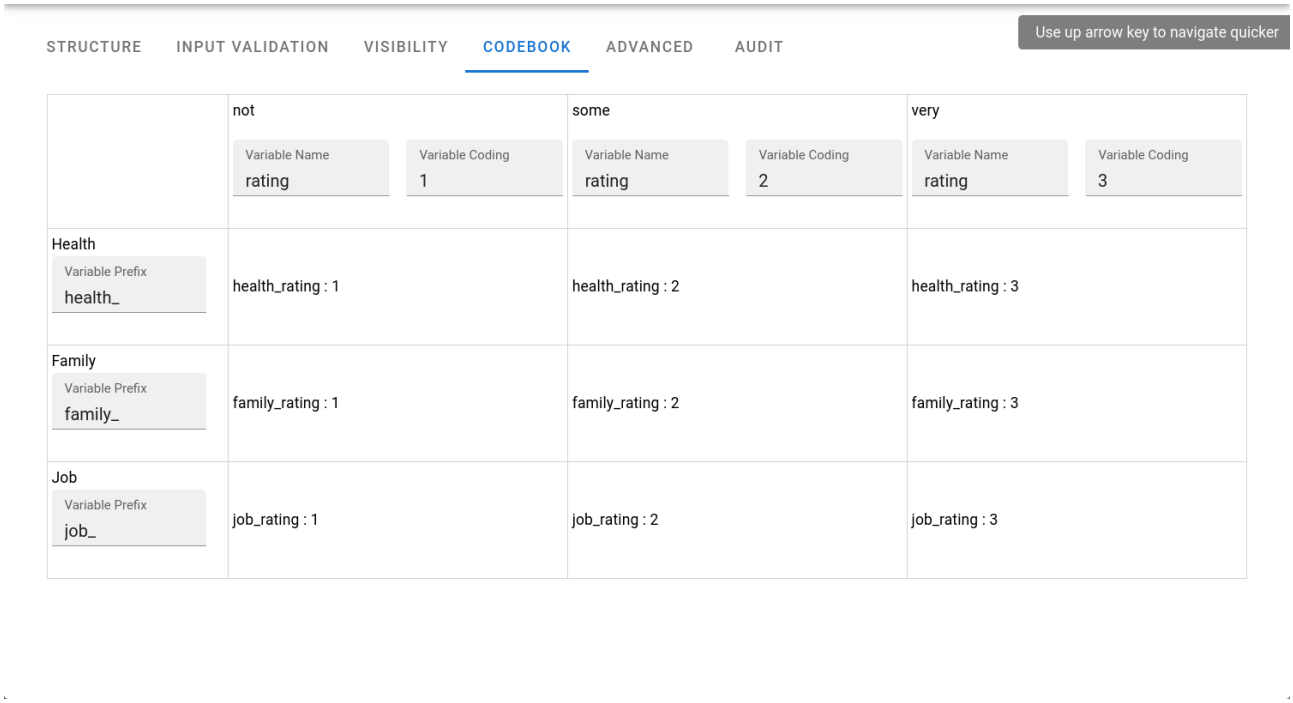
4.10.3 Variables in tables

Tables are collections of multiple variables. Accordingly, the same rules as for normal question/variable types apply. However, there needs to be a way to differentiate between the rows. In order to do that, the codebook for tables allows adding row-prefixes so that identification of individual items is easy and clear.

Example: We have a simple table with three checkboxes in the same group:



In order to get readable variable names we set the row prefixes `health_`, `family_` and `job_` and use the same column names while using different coding values as we would for a single choice question:



4.11 Advanced

In the tab "Advanced" you can set the question to *hidden* depending on the context in which the form is filled in (inhouse vs survey)

4.12 Audit

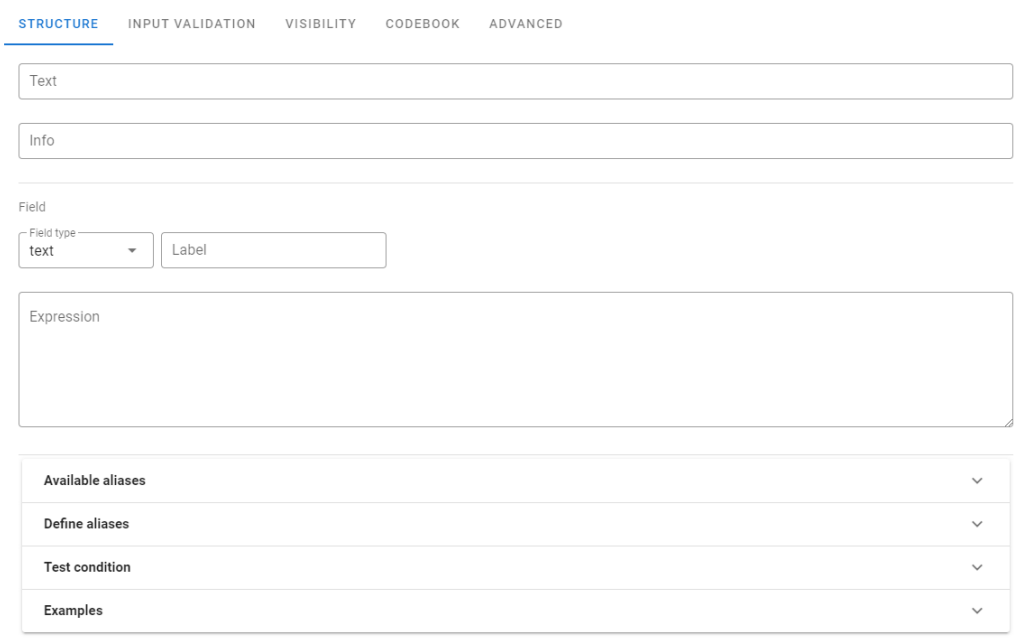
In this tab you can see all audit trail entries with respect to changes to structure and content of the question.

4.13 Computed fields

Computed fields are a powerful tool for automatic calculations based on data entered into a form. Common applications range from simple computation of mathematical equations (e.g. body mass index or GFR) to complex evaluations of conditions across several fields, forms and visits. The expressions for computed fields are written in MaganaScript.

The form designer interface of a computed field contains the following sections:

- Top section in which you write the expression to evaluate
- Available Aliases: A list of aliases that where already defined and can be used in expressions
- Define Aliases: Define new aliases and visit aliases
- Test condition: test the expression on a (test-)participant that is already part of the study
- Examples: Some examples of how to use expressions in computed fields


STRUCTURE
INPUT VALIDATION
VISIBILITY
CODEBOOK
ADVANCED
Text
Info
Field
Field type
text
Label
Expression
Available aliases
Define aliases
Test condition
Examples

5 MaganaScript

MaganaScript is a sandboxed subset of JavaScript. So it uses all the basic syntax rules of JavaScript. For security reasons, only basic language elements are available directly and specific features are provided through custom functions. The MaganaScript engine is used in several places of our software

- Computed fields
- Custom visibility rules
- Custom input validations
- Date window calculations in the visit scheduler module

5.1 Aliases

In order to use a value that has been entered into a case report form, you need to give it a unique name – an *alias* by which you can then refer to that value.

You can think of aliases as variable names but it is important to remember that aliases are not the same as the variable names defined in the codebook: Aliases are used in computed fields and complex conditions – variable names from the codebook determine the column names in the data export. We keep these separate intentionally, because an organization may have specific formal requirements for variable names for statistical analysis that may be hard to remember or follow by the staff programming computed fields and conditions in the eCRF. In many cases, it will make sense to use the same identifier for both variable name and alias for a data field but always keep in mind that codebook and aliases live in separate spaces names and may differ.

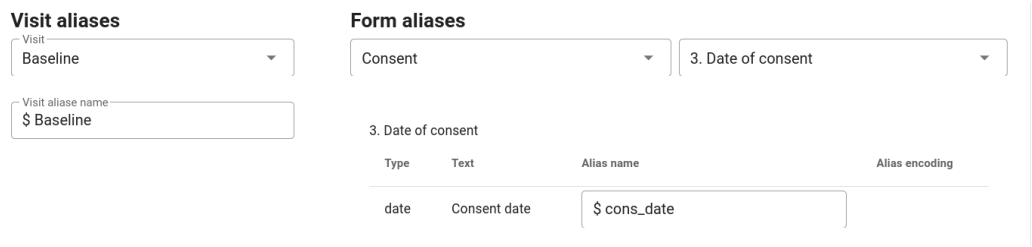
Aliases always start with a dollar character ($) and can only contain letters (upper and lower case), digits and the underscore character (_). Aliases are case sensitive, so `$Age` and `$age` are two separate things.

Aliases should be easy to understand – i.e. they should be short but clearly express what they contain. E.g. a good alias for the participant's age at the time of inclusion would be `$inclusion_age`, `$age_at_inclusion` or `$InclusionAge`, maybe also simply `$age` in case no other age is used in the study. Names that are hard to understand and remember should be avoided – e.g. `$a`, `$x`, `$iage` or `$aai`.

Aliases are defined on the form level. As long as each form is used only in a single visit, the naming scheme described above is sufficient. However, many studies use the same form in several visits – e.g. to collect follow-up data on the same topic. In that case, it is important to unambiguously refer to the value *in a specific visit*. This is accomplished by defining appropriate *visit-aliases* such as `$Baseline`, `$6m_followup` or `$after_intervention`. You can then use composite aliases in the form `$Visit.value`, where *Visit* is the visit alias and *value* is the alias for the specific value in a form. E.g.: `$Baseline.age`, `$3m_followup.cholesterol` or `$post_intervention.heart_rate`.

If a form is used only in a single visit, no visit alias is required. If a form is used in multiple visits and the visit-alias is not explicitly given, the program will assume that you want the value in the current visit (i.e. the visit in which the computed field is evaluated).

You can define your aliases in the *Define Alias* section of the computed fields designer interface. The leading $ character is already present in the definition form, so you do not need to type it yourself:



While you can use an alias to read the value of a certain question, there is no way to write to an alias. I.e. you cannot put data into a form by assigning a value to an alias.

5.2 Reserved Alias Names

User defined aliases must not start with an underscore (`$_`) because this is reserved for system special aliases that allow access to internal states and values. Currently, the following special aliases are available:

- `$_participant_identifier`
- `$_participant_status`
- `$_center_name`
- `$_center_timezone`
- `$_form_name`
- `$_visit_name`
- `$_randomization_group`

All of these can be used just like any other alias – i.e. for evaluations in computed fields or as part of advanced visibility rules.

5.3 Arithmetics

The following common mathematical operations are currently supported:

- basic arithmetics: `+ - * /`
- power: `x**y`
- square root: `sqrt()`
- modulo operator: `x % y`

Evaluation is carried out according to the normal preference rules. I.e. multiplication and division are carried out before addition or subtraction. You can use parentheses to group operations and change the order of evaluation.

Examples

```
// area of a circle
r**2 * 3.141593

// Pythagorean triangle
c = sqrt(a**2 + b**2)
```

5.4 Variables

When your computations become more complex it may be useful to define your own variables like this:

```
color = "red"
weight = 75
dose = 500
```

And use them:

```
dose_per_kg = dose / weight
```

Variable names must start with a letter and may consist of letters, numbers and the underscore character (_).

Please note that these variables are *local* – i.e. they only exist in the computed field where they were defined. They are not accessible in other computed fields or visibility rules etc.

5.5 Arrays / Lists

You can combine multiple elements like numbers or strings in arrays:

```
colors = ["red", "blue", "green"]
foo = ["A", 12, "foobar"]
```

To access elements of an array use the position of the element you want. Element numbering starts at 0.

```
colors[0] // returns "red"
colors[2] // returns "green"
```

The same method can be used to get specific elements of a string. E.g.:

```
foo = "Hello!"
hello[2] // returns "l"
```

To join all elements of an array into a string, use the `array_join` function. It expects two arguments:

ARRAY The array to join
DELIM The delimiter to use for joining. This can be a single character or a string.

```
array_join(ARRAY, DELIM)
```

E.g.

```
array_join([1,2,3], ", ")               # "1, 2, 3"
array_join(["A", "B", "C", "D"], "-")   # "A-B-C-D"
# Using an alias generated from a catalog question
array_join($ICD10, ";")
```

In order to test, if an array contains a specific element, use the `array_includes` function. It expects two arguments:

ARRAY The array to search

ITEM The item to look for

array_includes(ARRAY, ITEM)

E.g.

```
array_includes([1,2,3,4,5], 3)              # true
array_includes([1,2,3,4,5], 9)              # false
array_includes(["foo", 4, "bar"], "foo")    # true
array_includes(["foo", 4, "bar"], "FOO")    # false
array_includes(["foo", 4, "bar"], 0)        # false
```

5.6 Comments

Sometimes you may want to add some explanation or comment to your code. You can easily do that: All text after a double slash (//) until the end of line will be ignored during evaluation.

Examples

Convert from centimeters to meters:

```
$height / 100
```

Test if a number is even or odd using the modulus operator:

```
$number % 2       // true if $number is odd
$number % 2 == 0  // true if $number is even
```

Compute cardiac output in visit one:

```
// cardiac output
$V1.stroke_volume * $V1.heart_rate
```

Absolute weight change since inclusion:

```
$6m_followup.weight - $Baseline.weight
```

Percent change in weight since inclusion:

```
// percent weight change
$6m_followup.weight / $Baseline.weight * 100
```

Percent change in cardiac output from visit one to visit 2:

```
($V2.stroke_volume * $V2.heart_rate) / ($V1.stroke_volume * $V1.heart_rate) * 100
```

Body mass index:

```
$weight / ($height/100)**2
```

You can use white space for easier human perception but you do not have to. The following are equivalent:

```
$weight / ($height/100)**2
$weight/($height/100)**2
$weight / ($height / 100) ** 2
```

Numerical results can be rounded to the desired number of decimals – e.g. to one:

```
round($weight / $height**2, 1)  // only return one decimal
```

5.7 Logical expressions and conditions

You can use logical comparisons, conditions and if-statements to evaluate and react to certain conditions:

- Test for equality: `==`
- Test for inequality `!=`
- Test for greater/less than `>` `<`
- Test for greater/less or equal `>=` `<=`
- Logical and: `&&`
- Logical or: `||`
- Logical not (negation): `!`

Used by themselves, these operators return a value that is either *true* or *false*. E.g.

```
3**3 > 3+3  // true
```

In order to do something more useful with the result, you can use if-statements:

```
if ($Age < 18) {
    "Please use the Schwartz Bedside equation for GFR estimation"
} else {
    "Use the CKD-EPI Creatinine equation for GFR estimation"
}
```

In the above example, the value returned by the computed field is a text (string) defined by the age of that patient. There is also a shorter form to get the same result:

```
$age < 18 ? "Schwartz Bedside" : "CKD-EPI"
```

The general format is: `CONDITION ? True_Result : False_result`

Complex conditions can be constructed using logical operators:

```
if ($Age>=65 || ($BMI<18 && $no_appetite=="yes") ) {
    "Check for XXX"
}
```

5.8 Dates and Times

Sometimes, you may want to work with dates and especially date differences. E.g. to determine the time since inclusion, between visits etc. The system offers a number of functions to do this.

A few words of caution:

Date operations are quite complex by nature. The most important concept to understand is that *dates* really are points in time (timestamps / datetimes) that contain both the calendar date and a time, even if that is not visible in many cases. E.g. internally, the date 05/23/2021 (MM/DD/YYYY) has the time 00:00 attached to it. In fact, the time information is even stored to sub-second precision. I.e. the current date will be something like "2021-07-04T13:51:30.595Z".

Furthermore, such a date refers to UTC (Universal Time Coordinated) – formerly known as GMT (Greenwich Mean Time), not your local time zone. This is important to remember, especially if your study centers are located in *different time zones*.

Carefully test all date operations with lots of examples including edge cases such as "the same day", "an hour later", etc.

The following operations are supported:

- `date_now()` – date and time *now*
- `date_diff($date1, $date2, UNIT)` – the difference between two dates
- `date_add($date1, K, UNIT)` – add *k units* to a date
- `date_subtract($date1, K, UNIT)` – subtract *k units* from a date
- `date_format($date1, FORMAT)` – pretty print a date in the desired format
- `date_format_tz($date1, FORMAT, TIMEZONE)` – pretty print date after converting to *TIMEZONE*

Time zone names look something like this: "America/New_York", "Asia/Tokyo" or "Etc/GMT+2". Valid timezone names are standardized and a complete list can be found here.

where

- *K* is a number
- *UNIT* is one of "second", "minute", "hour", "day", "week", "month", "year"
  Keep in mind, that a month may have different numbers of days
- FORMAT is a string (text) describing how the elements of a date are to be formatted.
  E.g. `DD.MM.YYYY HH:mm` for the format commonly used in most of Europe or `YYYY-MM-DD` for data in ISO format.
  Valid placeholders are:
  - `YYYY` – four digit year
  - `YY` – two digit year
  - `M` – month
  - `MM` – two digit month
  - `D` – day
  - `DD` – two digits day
  - `h` – hours (12 hour format)
  - `hh` – two digit hours (12 hour format)
  - `H` – hours (24 hour format)
  - `HH` – two digit hours (24 hour format)
  - `m` – minutes
  - `mm` – two digit minutes
  - `s` – seconds
  - `ss` – two digit seconds

- `a` – am/pm
- `d` – numeric day of the week (1 = Monday)
- `dd` – day of the week, two letters (e.g. "Tu")
- `ddd` – day of the week, three letters (e.g. "Tue")
- `dddd` – day of the week in full (e.g. "Tuesday")
- `/ . - : , ; \_ + !"` – allowed delimiters for date and time

Date Examples

Results of each operation are given in the comment "//".

Get the current date and time:

```
date_now()
// 2021-07-04T14:27:30.595Z
date_format(date_now(), "DD.MM.YYYY HH:mm")
// 04.07.2021 14:37
date_format_tz(date_now(), "DD.MM.YYYY HH:mm", "EUROPE/BERLIN")
// 04.07.2021 16:37
```

How long ago was the baseline visit?

```
date_diff(date_now, $Baseline.date)
// 482887476
```

By default, the result above is in milliseconds! So let's make that a little easier to understand:

```
date_diff(date_now(), $cons_date, "hour")
// 134
date_diff(date_now(), $cons_date, "day")
// 5
date_diff(date_now(), $cons_date, "week")
// 0
```

Now, let's manually check that:

482887476 ms / *1000* / *60* / *60* / *24* = *5.588975* days

Everything is rounded to the *full* week/day/hour etc. So when you last saw your participant yesterday at 10:00 a.m. and it is now 8:00 a.m., the time difference in days is 0! Keep that in mind, when setting up date operations.

To gain more control, you could compute the difference in fractional days:

```
date_diff(date_now(), $cons_date, "hours") / 24
// 5.583333333333333
date_diff($cons_date, date_now(), "hour") /24
// -5.58333333333333
round(date_diff(date_now(), $cons_date, "hour") /24, 1)
// 5.6
```

Practical application: Checking date windows

Let's assume you want to check, if a visit actually happened in the time window required by your protocol:

- *Inclusion*
- *1st Follow-up* must take place 7-14 days after inclusion
- *2nd Follow-up* must take place 30-40 days after *1st Follow-up*

You have a form *Visit date* that is assigned to all visits and ask for the visit date. Now we want to check if the visit window was obeyed and issue a warning otherwise.

First, we define a visit alias for each of them:

- *Inclusion*: `$V0`
- *1st Follow-up*: `$V1`
- *2nd Follow-up*: `$V2`

and assign the alias `$vdate` to the date field in the *Visit date* form.

Now we can add a computed field to the *visit date* form that checks the time differences and issues the warning message:

```
window_ok = true
if ($_visit_name == "1st Follow-up") {
    window_ok = 7 <= date_diff($vdate, $V0.vdate, "day") <= 14
} else if ($_visit_name == "2nd Follow-up") {
    window_ok = 30 <= date_diff($vdate, $V1.vdate, "day") <= 40
}
window_ok ? "" : "<b style='color:red'>Visit date is outside the allowed time window!</b>"
```

5.8.1 Times

As of writing, there are no explicit time functions. However, the `date*` functions described above actually work on datetimes. So in order to e.g. calculate time differences, you can expand the time values to complete datetimes and then use the `date*` functions:

```
# $t0 is the Starting Time (entered in a form)
# $t1 is the Ending Time (entered in a form)

# attach an arbitrary date and computethe difference
dd = "2000-01-01T"
delta_t = date_diff(dd + $t1, dd + $t0, "minutes")
```

5.9 Strings

Sometimes you want to convert an entire string to upper or lower case – e.g. for easier comparison to an expected value. You can do that like this:

```
    lower($drug) == "ibuprofen"
```

or

```
upper($drug) == "IBUPROFEN"
```

In order to get the letter at a specific position of a string you can use indexing:

```
foo = "ABCDEFG"
foo[2]  // "C"
```

remember that indexing starts at 0.

You can also concatenate several strings into one:

```
foo = "ABCD"
bar = "efg"
"letters: " + foo + bar   // "letters: ABCDefg"
```

This can be useful to construct the output of computed fields from several aliases or computations:

```
result = "<ol>"
result += "<li> Visit 1:" + $v1.weight * " kg </li>"
result += "<li> Visit 2:" + $v2.weight * " kg </li>"
result += "</ol>"
result
```

5.10 Regular Expressions

Regular expressions represent a way to test if a string follows certain composition rules or contains a specific pattern. Function `regex_test` takes a two arguments:

1. A string to be tested
2. A regular expression definition.

The function returns `true` if the regular expression matches the string, `false` otherwise. The syntax of the regular expression follows the definition for ECMA Script (Javascript).

A regular expression is delimeted by two slashes (`/`) between which the pattern is contained. The pattern can contain normal text and special tokens. E.G. `/foo/` matches any string that contains the substring "`foo`" and `/foo.*bar/` matches "`foobar`", "`foo bar`" or "`foo and bar`" etc.

Important RegEx tokens

token	Description
`.`	Any character
`\.`	A dot (`.`)
`[abc]`	Any of the characters `a`, `b` and `c`
`[a-zA-Z]`	any letter of the alphabet, upper or lower case
`[0-9]`	a digit
`\d`	a digit
`[aeiouAEIOU]`	a vowel
`[^aeiouAEIOU]`	not a vowel

token	Description
`\n`	newline
`\r`	carriage return
`^`	Beginning of string or line
`$`	End of string or line
`\b`	Word boundary
`*`	zero or more repetitions of the token before it. E.g. none or many `X`: `X*`
`+`	one or more repetitions of the token before it. E.g. one or many `t`: `t+`
`?`	zero or one of the token before it
`{5,}`	five or more repetitions of the token before
`{0,5}`	up to five repetitions of the token before
`{3,5}`	tree to five repetitions of the token before
`{5}`	exactly five repetitions of the token before

5.10.1 Practical use

Regular expression matching can be applied to strings that are given verbatim in the function or that have been defined elsewhere. This also includes *aliases*. Some examples:

```
regex_test("MaganaMed", /aga/)  // true

color = "green"
regex_test(color, /re/)         // true

regex_test($other_condition, /infection/)
```

In the following, we show a few practical examples that illustrate what you can accomplish with regular expressions.

- Contains the word *color* in American or British English:

  `/colou?r/`

  matches "favorite colour" as well as "color coded"

- Exactly matches the word *color* in American or British English:

  `/^colou?r$/`

  matches "color" and "colour" but not "color code" or "dark color"

- Contains *color* in US or British spelling, even at the beginning of sentence:

  `/[Cc]olou?r/`

- Match `Google` allowing it to be stretched with arbitrary many o's in the middle:

  `/Go{2,}gle/`

- Match a string that adheres to the pattern `dddd.ddd-XX/dddd`, where `d` is a digit and `X` is an upper case letter:

  `/^\d{4}\.\d{3}-[A-Z]{2}\/\d{4}$/`

- Naive (and incomplete) check, if string is an email address:

  `/^[a-zA-Z.+\-]+@([a-zA-Z\-]+\.)+[a-zA-Z\-]+$/`

- Slightly better email check:

  ```
  /^\S+@(\S+\.)+\S+$/
  ```

- A valid weekday

  ```
  /^(mon(day){0,1}|tue(sday){0,1}|wed(nesday){0,1}|thu(rsday){0,1}|fri(day){0,1}|
  sat(urday){0,1}|sun(day){0,1})$/
  ```

- German ZIP code (5 digits)

  ```
  /^\d{5}$/
  ```

For more token definitions and to try out regular expressions interactively, go to rexex101.com and select *ECMA Script (JavaScript)*.

5.11 Advanced operations

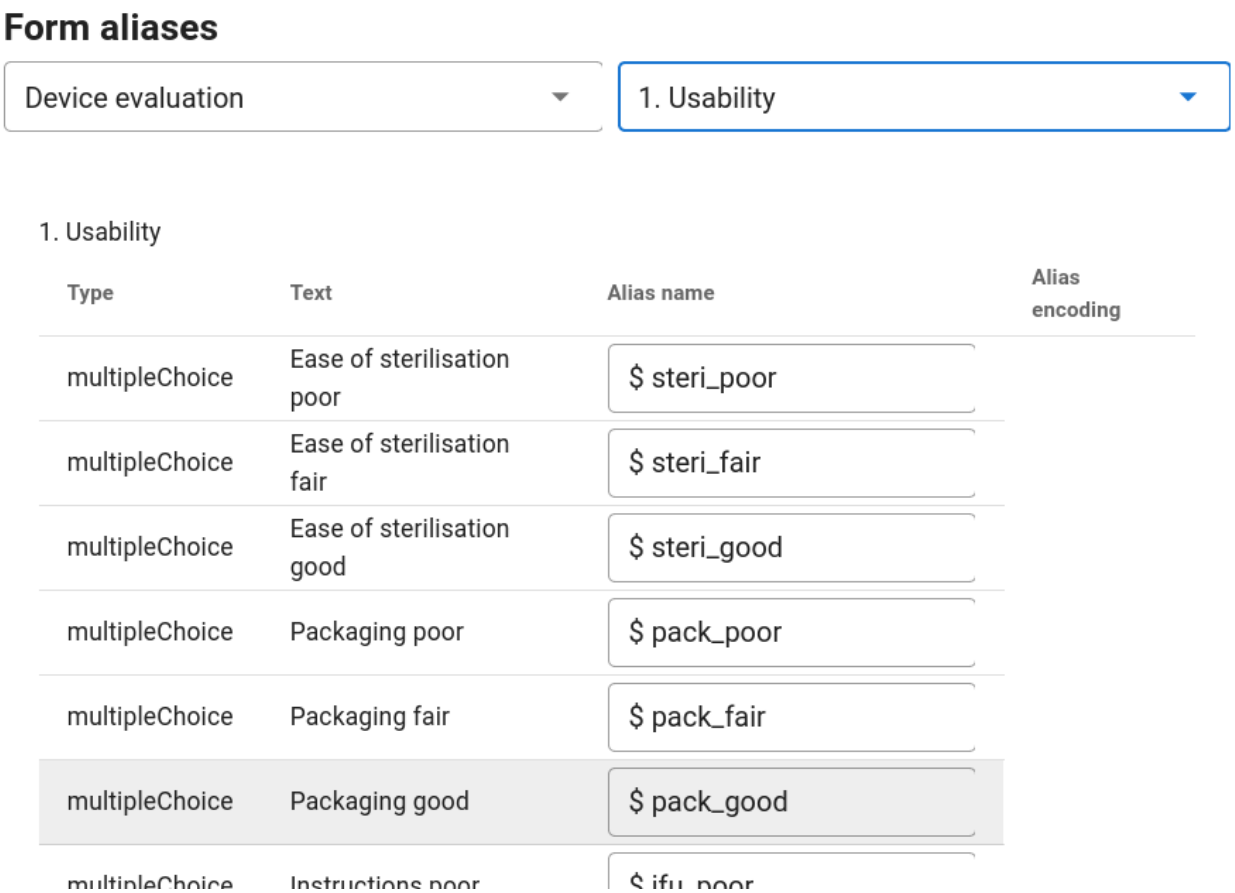
Let's assume you have a table for rating different aspects of a medical device:

1. Usability

Please rate the following aspects of the device.

	poor	fair	good
Ease of sterilisation	☐	☐	☐
Packaging	☐	☐	☐
Instructions	☐	☐	☐
Handling	☐	☐	☐

We want to compute a rating score where each "poor" answer is worth 0 points, "fair" yields 1 point and "good" 2. In order to use these variables, we need to define aliases in our computed field:



Next, we need a way to get different values depending on the category (poor/fair/good). We can use a short expression that works very similar to an if statement:

```
$steri_fair ? 1 : 0     // returns 1 if steri_fair==true and 0 otherwise
$steri_good ? 2 : 0     // returns 2 if steri_good==true and 0 otherwise
```

Now, we can set up an expression to compute the score:

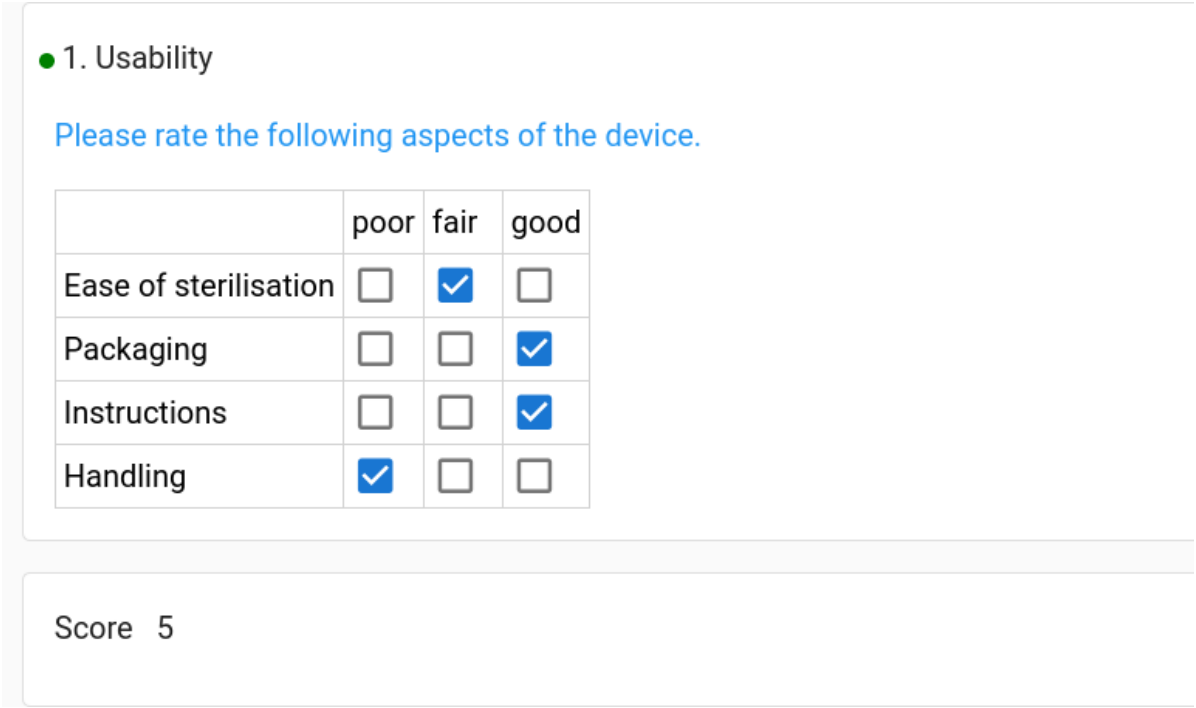
```
score = 0       // initialize score with zero
score = score + $steri_fair ? 1 : 0
score = score + $steri_good ? 2 : 0
score = score + $pack_fair ? 1 : 0
score = score + $pack_good ? 2 : 0
score = score + $ifu_fair ? 1 : 0
score = score + $ifu_good ? 2 : 0
score = score + $handling_fair ? 1 : 0
score = score + $handling_good ? 2 : 0
score // return the value of the score
```

Here, we are using a new concept: In the first line, a local variable is defined. Please note that the variable *score* does not start with a dollar character. That means that it does not refer to anything entered into a form but is only used in the context of the computed field. In the example, it is used to set the score to zero before we start checking conditions. The subsequent lines test a series of conditions and return the respective value. This value is then added to the score and the value assigned back to the *score* variable (+= operator). Finally, the last line evaluates to the score at that point and returns this as the value of our computed field.

The above code can be written in a simplified way, by using the += operator: Instead of explicitly adding something to the score and then assigning the result back to the score variable, += does it in one step:

```
score = 0   // initialize score with zero
score += $steri_fair ? 1 : 0
score += $steri_good ? 2 : 0
score += $pack_fair ? 1 : 0
score += $pack_good ? 2 : 0
score += $ifu_fair ? 1 : 0
score += $ifu_good ? 2 : 0
score += $handling_fair ? 1 : 0
score += $handling_good ? 2 : 0
score       // return the value of the score
```

For all these approaches, the result is the same and looks like this:



6 Creating visits

A visit is every touching point with the participant to obtain clinical data. Thus, every form is assigned to one or more visits. Similar to a question in a form, also a visit can become necessary only in dependence on certain circumstances. Also this dependent visibility can be defined.

6.1 Add, move, edit and delete a visit

Add a visit

To add a visit go to setup → visit and click on the blue button named "add visit". Assign a name and click "save".

Setting the order of visits

To change the order of visits click and hold the crossed arrows symbol and move the visit to the desired location.

Edit a visit / define visit settings

To edit a visit and to set all options click on the pen symbol at the right side of the visit box. Here you can also change the name of the visit and define if the form will be filled in by the study team (in-house) or by the participant (survey).

Delete a visit

To delete a visit, click on the bin symbol at the right side of the visit box. Confirm the deletion. This step cannot be undone.

6.2 Assigning forms to a visit

Every form has to be assigned to a visit to be available at the right time point to the right group of participants. To assign a form to a visit:

- enter the edit mode of the visit by clicking the pen symbol at the right side of the visit box
- click on "select form" and choose the form which you want to connect with the visit
- Click "add"

To add more forms to the same visit, repeat all steps.

To change the order of the forms, click and hold the crossed arrows symbol next to the name of the form and move it into desired order.

6.3 In-house visits, surveys and diaries

If the survey module is active, you can set the type of the visit in the visit setup view:

The default type of a visit is the traditional *in-house* visit. I.e. the participants visits the study site and forms are filled in by professional site users such as study nurses and physicians.

Sometimes, a study contains visits that do not require the participants to come to the study site and fill in forms themselves, instead. In Magana TrialManager this kind of visit is called a *survey visit*. In that setting, the participant receives a link to his or her form so they can enter their own data. Typically, the link is sent by email. This feature is used for various purposes: Quality of life questionnaires, ePRO/eCOA and many others.

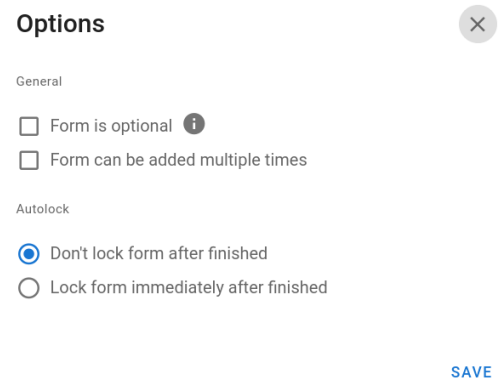
Diaries are similar to survey visits in that they are filled in by participants not site personnel. Diaries allow filling in the same form over and over again, so that participants can document symptoms over time – e.g. daily.

6.4 Form properties in visits

For each form that you assigned to a visit, there is a context menu next to it that allows to carry out a few actions o the form.

Options

Under *Options*, you can set a few different form properties:



Form is optional If this option is selected, the form will not be available by default. Instead, You need to Click *Add Form* in the participant view to activate this form. a typical use case are forms that are only used for selected participants and the site personnel shall be responsible to decide if it is needed. This is alternative to automatically hide/show a form based on visibility criteria.

Form can be added multiple times Selecting this option allows a form to be added to a visit more than once by site users. Example: In an intervention visit, you want to have one copy of the *Stent* Form for each stent that was implanted. As you don't know in advance, how many stents will be implanted, this option gives you the required flexibility.

If it is possilbe tha tno stent is implanted at all, you can combine this option with the previous option.

Lock/Don't lock form at finish Selecting the *Lock form after finished* option will activate the *autolock* feature of the system

Delete Form

This item removes the form from this visit.

Visibility

In this item, you can define conditions that must be met in order for the form to be shown in this visit. Example: Only show the prostate examiation form for male participants.

See Visibility of Visits for details on how to define the condition.

6.5 Visibility of visits

Similar to questions in forms it is sometimes necessary to view a visit only under certain circumstances, which not every participant receives.

To enter the visibility settings go to setup → visits → pen symbol of respective visit → three dots at the right side of the respective form → configure visibility

Enter conditions

Define your condition in the respective field. Following operators are allowed:

```
&& || ! () < > =
```

All variables must start with a $ in formulas; e.g if your variable is called "weight" you have to use the expression `$weight` in your formular.

Examples:

```
($a1 && $a2) || ($a3)
```

Questionnaire will be shown if answer 1 and answer 2 are checked or answer 3

```
($a1 != 1)
```

Questionnaire will be shown if answer 1 value is not equal 1

```
($a1 >= 1)
```

Questionnaire will be shown if answer 1 value is larger or equal 1

```
center_name == "center 1"
```

Visit will only be shown to participants of center 1

Setting aliases

To support the definition, you can use aliases for every question. Note that the aliases will also be used in computed fields. Thus, a change of an alias will also affect computed fields.

Test condition

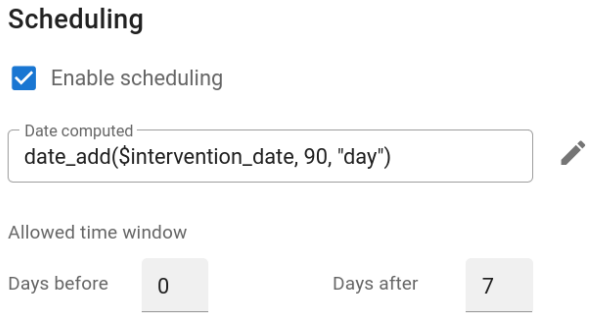
The setting of dependent visibilities can become complex. Thus, this option allows you to test the functionality of your settings on selected participants. We recommend creating at least two test participants of whom one shall receive the visit and one shouldn't.

Defining a condition for the first time can be difficult. If you need any assistance contact us at info@maganamed.com.

6.6 Visit scheduler

Using the *visit scheduler* module, it is possible to define time windows for visits depending on reference dates (e.g. day of inclusion).

1. Enter the visit setup
2. Select *enable scheduling*
3. Enter expression into the *date computed* field. Typically, you would want a fixed time after some other event. E.g. 30 days after the *Intervention* visit:
   `date_add($date_intervention, 30, "day")`
   or
   `date_add($Vintervention.date, 30, "day")`
   Of course, you need to define the alias `$date_intervention` or the aliases `$Vintervention` and `$date` associated with a date field in the appropriate form and visit. See MaganaScript for details on the syntax of these computations.
4. Define the allowed time window before and after the calculated date as defined in your study protocol. E.g. something like ±5 days.



The definition of the time window for the visit will result in the display of the target date next to the visit name for each patient in the patient details screen.

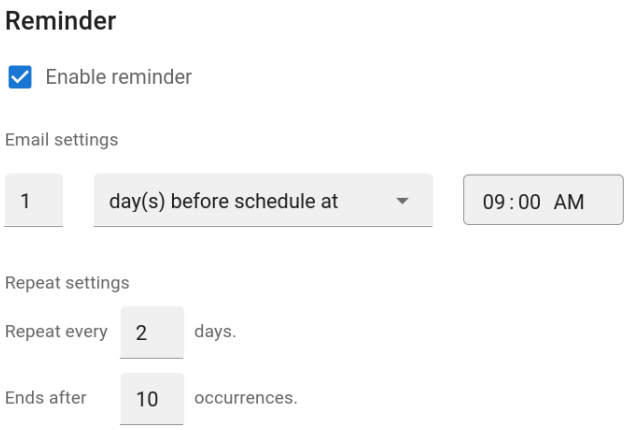
All scheduled dates can be accessed in the calendar, which can be accessed via the navigation panel on the left.

Automatic visit reminder

Participants can get automatically reminded on scheduled visits.

To set-up an automatic reminder for a specific visit:

1. Enter the visit setup
2. Set-up a scheduled visit
3. Select *enable reminder*
4. Define the time point of the first automatic reminder email
5. Set the number frequency of the reminders



An active reminder for a participant is indicated by a green light in the participant detail screen in the section “reminder”. If the reminder is inactive (orange light), no email is defined for that participant. Please enter an email in the section “edit identity”

Notes:

- a participant can only be reminded, if an email address is saved with the participant
- an email can only be saved with the participant, if the user has the “identity” permission
- The reminder log will log all time points of sent out emails

7 CRF review and Go-Live

Before setting your study live we highly recommend to test all settings. While MaganaMed validates the functionality of our software, customers are responsible for validating the eCRFs they set up in the system.

In the following we summarize some tips for ensuring a smooth start of the recruiting phase.

- **Test EVERY step.** It will take a little bit longer, but every error in the workflow will cause a lot of work and pressure once the study is live.
- **Create several test participants** and test all features and settings. All participants created during the setup phase can be automatically deleted during the going-live process
- **Let colleagues test, too.** The creator of the study very often is too deeply involved in the study workflow thus cannot spot inconsistencies reliably enough anymore.
- **Use the pdf version of forms for proof-reading.** Even if the form will later only be used electronically, a printout is very often helpful to spot typos an other problems.
- **Don't just test the ideal path.** Make "Mistakes" – try entering unexpected or even invalid data, try to break the workflow you designed. That way you are most likely to identify setup mistakes and situations you didn't think of.

Ideally, conduct your testing in the context of an eCRF validation plan.

7.1 Going live

Once everything is set up and tested it's time to go live. To set the study live go to set up → go live.

- confirm by ticking the box that you really want to proceed and set the study live
- choose if you want to delete or keep all existing participants of the setup phase (deletion of the participants cannot be undone)
- Click: *GO LIVE!*

NOTE: You can only go live, if all billing information is completed and all booked modules are activated by MaganaMed. Please contact the team of MaganaMed for further information: support@maganamed.com

Going live has several consequences to your study:

- Every step is automatically tracked in the audit trail, which cannot be edited or deleted
- The setup options get hidden (can still be accessed by clicking on setup)

After going live, the button will change to "Lock study". Use this button at the end of your study, to freeze all data and stop the payment period. All data will be "read-only" but can still be exported.

7.2 Changes after Go-Live

Making changes to the CRF after go-live is possible but must be done with great care in order to prevent problems or inconsistencies. The system will impose some restrictions on changes to prevent accidental edits and we recommend to follow re recommendations in this section.

7.2.1 Changing forms

Changing the content of a form that is already being used is problematic and should be avoided except for very minor edits such as correcting simple typos that have no risk of changing the meaning of a question. It may be acceptable to add questions to a form because it does not affect previously entered data. However, you will have to make sure that study sites are informed that/if they are expected to add that data to forms they have already finished.

Furthermore, the system will refuse changes to forms that already carry signatures. If you really must edit such forms, you have to remove all signatures on that form in all visits before the system will allow edits.

This restriction can be deactivated under *Setup* > *General* > *Regulatory* but we strongly discourage doing that because it is most likely not compliant with GCP to do that. At the very least, make sure to document that decision well! But really: don't use it!

The recommended way to make any non-trivial changes to forms is to make the changes outside the live study and copy them into the live study after validation of the adapted or new form.

1. Create your Edit-Environment:
   - Create a new study.
   - Copy the form you want to change to the new study.

     – *OR* –
   - Contact support to make full copy your live-study (without data).
   - In the copy, Make a copy of the form you wish to change.
2. Rename the copy of your form to clearly indicate that it is a newer version. E.g. "Demographics v2.0" or similar.
3. Make the intended changes to the new version of the form.
4. Test and review your copy in the preview.
5. Add the changed form to the appropriate visits.
6. Remove the old version of the form from the appropriate visits.
7. Validate the new form with test-participants.

Once validation of the new form has finished:

1. Copy the new form from the edit-study to the live study.
2. Rename the old version of the form appropriately (e.g. "Demographics v1.0").
3. Remove the old version of the form from the appropriate visits. We recommend not to "delete" the old form. Any data that was entered into the form before being unlinked from the visits will, of course, remain in the database.
4. Add the new form to the appropriate visits. If necessary, adapt visibility rules and computed fields that use data from the new form version.

7.3 Closing the study

After the last participant has finished the study and is fully documented, there are usually a few things to finish before the study can be closed:

- Closing remaining queries
- Remaining monitoring activities
- Signing forms
- Exporting all data
- ...

When all of these activities are done, it is time to close the study. To do so, click to *Go-Live* > *Lock study* and confirm that you want to loch the entire study. After locking, the study is read-only, i.e. you can still view all data an export it but you can no longer edit participants or data, edit queries, sign, add verifications etc.

Caution: Once locked, you cannot unlock the study anymore, so make sure you do that only when you are 100% sure everything is final and no further editing is required.

Locking the study is important, to document that it is finished – for your own documentation but also to tell the system, that the study is no longer active and has ended within the booked period of time.

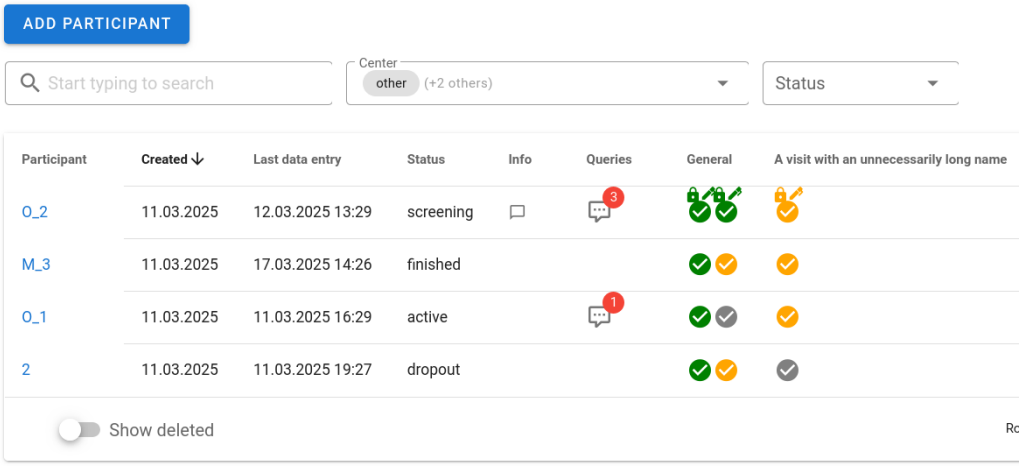
8 Managing participants

Once the study is live, we are in the recruiting phase of the study. However, many of the functions intended for the recruiting phase should be used during CRF validation and/or user acceptance testing.

Recruiting phase is the phase of active data collection. Every step and action is automatically tracked in the audit trail. You can view the current recruiting status and the last changes in the audit trail via recruiting → overview at any time.

8.1 Participant list

The participant list is available form the respective entry of the main menu. It shows a complete list of all participants, you have access permissions for (i.e. your center(s)).



The list can be *filtered* by multiple criteria including participant ID, center and participant status. The search field will accept searching for participant IDs and also complete survey-login identifieres (partial identifieres will not match).

The list can be *sorted* by any of the following criteria by clicking on the respective header. Clicking again will reverse the sorting order.

- Participant ID
- Creation date
- Date of last data entry
- Participant status
- Presence of notes/info
- Presence of queries

Clicking on the participant ID will directly take you to the participant view for the respective patient. Clicking on a form symbol (check mark) takes you directly into the form of that participant.

The system will remember filter and sorting settings as long as you just click on items in the view and return to the overview using the *Back* button of your browser. Opening other menus in the system and returning to the participant list by clicking *Participants* in the menu will reset all filters.

Your role in the study and the permissions associated with it determine what kind of access you have: Users only have access to participant(s) in their own center(s).

Forms can have different states:

Gray checkmark symbol The form has been assigned to the participant but processing hasn't started, yet.
Yellow checkmark symbol The form is in progress but not all required answers have been entered, yet and/or the site users ahve not clicked *finished*, yet.
Green checkmark symbol The form has been finished.

In addition to the main status indicator, there can be additional symbols:

Padlock A padlock indicates that the form has been locked. No further data can be entered. Only users with respective permissions can unlock the form to add additional data.
Pen A pen symbol indicates that the form has been signed.
Double checkmark The green doiuble checkmark indicates that the form has been *verified*.

All of those are shown in the participant views, some also in the partcipant list.

8.2 Adding a participant

To add a participant go to recruiting → participants and click "add participant"

You automatically enter the participant screen.

8.3 Adding and editing participants' data

After adding a new participant you automatically will enter the participant screen. You can also enter the participant screen via recruiting → participants and clicking on the respective participant.

In the participant screen you can add and edit all data connected to the patient (if you have the needed permissions). You have following options:

Delete participant

The respective participant will be marked deleted. Documentation of a reason for deletion is mandatory. Additionally, participants can't be deleted completely but only marked as deleted during the recruiting phase. If you want to view deleted participants click on "show deleted participants" in the participants overview at recruiting → participants.

Only users with respective permissions can delete participants.

Participant status

A status can be assigned to each participant (e.g. "screening failure", "drop-out", etc.). Available status can be defined under setup → general → monitoring → participant status

To assign a predefined status to a participant, just click the drop-down menu below the participant ID and select the respective status from the list.

Generate survey login identifier (only surveys)

This will generate a unique identifier for this participant.

Comments

Enter a comment to this participant.

Visits: send survey (only surveys)

You can send the survey to the respective participant.

Visits: open/edit form

Manage all data in the context of the participants froms. More details see 3.2.2.

Files

Upload files connected to the participant.

History

Track of all changes of the patient.

9 Entering data

Data is typically entered by a user (e.g. the study nurse), who is logged into the system or directly by the participant with the survey or eDiary function.

All data that is entered into the forms of your eCRF will be saved to the database automatically, without the need to explicitly click a *save* button. However, each form has a *finish* button at the bottom. By pressing that button you indicate that you have entered all data into the form and it can be considered complete.

At the very top of the data entry page, you will find a row of text that indicates your exact position in the study. It contains

- Participant ID
- Visit name
- Form name

separated by > characters.

Many studies have multiple forms per visit and it can become cumbersome to enter each form of a visit separately for data entry. In order to make the data documentation easier, each form has a button *Finish and Next* at the end. Pressing that button will finish the form and automatically enter the next form. If you press this button in the last form of a visit, a dialog will pop up asking you if you really want to continue to the next visit. This is intended to prevent site users to accidentally enter data into future visits.

9.1 Data entry by site personnel

You can open a form of a participant by selecting the participant from the participant list and clicking the *open* button in the respective visit. As a shortcut, you can also find the desired visit and form of your participant directly in the participant list and click on one of the round check mark symbols in the list.

When entering a form, you will see a navigation bar on the left side of your window and the form on the right. The navigation bar allows efficient navigation between different forms, visits and even participants without having to go back to the participant view. The navbar will remember it position as long as you do not leave this data entry mode and simply move between forms and visits.

9.2 Changing data

As long as a form has not been finished, you can freely edit data. However, after clicking *finish*, any subsequent data entry or change requires justification. I.e. upon changing data, a dialogue will automatically pop up asking you to select a *reason for change* from a preconfigure list. In addition, you can also enter a free form comment in a comment field.

This feature can be deactivated by the study owner.

9.3 Data entry by study participants (Surveys/Diaries)

In some studies, participants are expected to enter (some) data themselves in participants *surveys* (ePRO, eCOA, etc) or *Diaries*. Forms intended for the participant are located in special visits that are marked as *survey* or *diary* in the participant view. Site personnel has access to these forms and can fill them in on behalf of the participant if necessary. However, the normal use of these visits is to send a survey invitation to the participants who will then complete the form(s) – typically on their own device.

Survey invitations can be sent in several ways and study administrators will configure the study accordingly (see section 3.8). In some scenarios, site personnel is expected to manually send survey invitations.

Manual email invitation

One way of doing that is to select *Send Email* in the *Participant login* box of the participant view:

- Select the correct visit you want to send an invitation to
- enter the participant's email address in to the `To` field
- Optional: edit the message (typically not desired)
- Click *Send*

Create printout for later use

Another method is creating and printing a document that contains the survey link for your participant and/or a corresponding QR code. If the study administrator has configured a suitable *print template*, site users can create such document by selecting *Print*. A preview of the page will pop up. Select the desired printer and click *Print*.

Give the printout to the participant and give instructions on when and how to open that link.

Quick QR-code access

In some situations, you want the participant to fill in the form now while he/she is present at the site. To do that, you can select *QR Login* in the *Participant login* field. A QR-code will be shown. Scan the QR code with a smartphone or tablet and follow the link. Hand the device to the participant for data collection.

The QR code on the computer screen will close automatically after a while, but you can also close it manually.

eDiaries work the same way but participants can use the "+" icon to add new form copies as needed (e.g. daily).

9.4 Retracting the *finished* state

By clicking *Finish* at the end of a form, the person entering data indicates that they have completed data entry for this form. The green status indicator signals to colleagues and monitors that the form is complete and ready for signing/locking/review. If you finished a form accidentally, you can revert its status by selecting *Mark as unfinished* in the context menu of the form in the participant view.

9.5 Locking and unlocking forms

Depending on the auto-lock settings, the form might get locked directly after completion. If manual locking of the form is required/set, go to recruiting → participants and enter the participant screen via clicking on the respective participant. Select the respected form by clicking on the three dots next to the form and select "lock".

You can only lock and unlock forms with the respective permissions.

9.6 Signing forms

To sign a form go to *recruiting* > *participants* and enter the participant screen via clicking on the respective participant. Select the respected form by clicking on the three dots next to the form and select *sign*.

To verify your identity you will have to enter your email address and your password again. To be compliant with applicable regulations, this step is required for each signature.

If you have the required permission, you can also lock the form at the same time by selecting the respective option.

Signing a form requires that the respective user has a role with signing permissions. The meaning of the signature (e.g. approval) is clearly indicated in the signature dialogue and can be configured by study admins (*Setup* > *General* > *Regulatory*).

9.7 Biosample management

Biosamples (e.g. serum, tissue, CSF) can be assigned to patients at the time point of collection in order to clearly link one or more samples to one patient.

You can access the biosample handling via *recruiting* > *biosamples*.

9.7.1 Biosample inventory

In the inventory all generated sample IDs are listed. Additionally, all available information on each sample like type, date of packing, tubes, the actual status of life cycle and a link to the assigned participant can be found in this section.

9.7.2 Packing of biosamples

If configured that way, before a sample ID can be assigned to a participant, the tubes have to be packed and registered in the system. This can only be done by staff with the permission "biosamples".

To access packing go to recruiting → biosamples → packing.

To pack a sample set, scan the created barcode or type in the generated ID of the respective sample set.

Note: Only generated IDs listed in the inventory can be used.

If the tubes have their own identifiers and this was selected during setup of the tubes, you can scan or type in the respective identifier in the subsequent steps.

Click save or press enter to mark the sample set as packed.

The packed sample sets can now be used in the study.

9.7.3 Using biosamples in the study

The workflow of biosample usage is aligned with the physical handling process of biosamples. Thus, using biosamples consists of following steps:

- open the respective patient in the trial manager (recruiting → participants → participant number)
- click in "add" in the section "Biosamples"
- take the sample set which you are going to use for this participant and scan (or type in) the identifier of the sample set ID (2D barcode on the sample set)
- click "add"

The biosample set is now assigned to the patient.

You can add further sample sets to the same patient if needed by following the same steps.

9.7.4 Biosample life cycle

The sample life cycle can be viewed and edited at two different places in the software:

1. recruiting → participants → select participant → biosample
2. recruiting → biosamples → inventory → column: life cycle

In order to view past status, just hover over the clock symbol next to the actual life cycle status. To change the status, click on the actual status and select from the drop down list (to set available status see point 3.1.2.4).

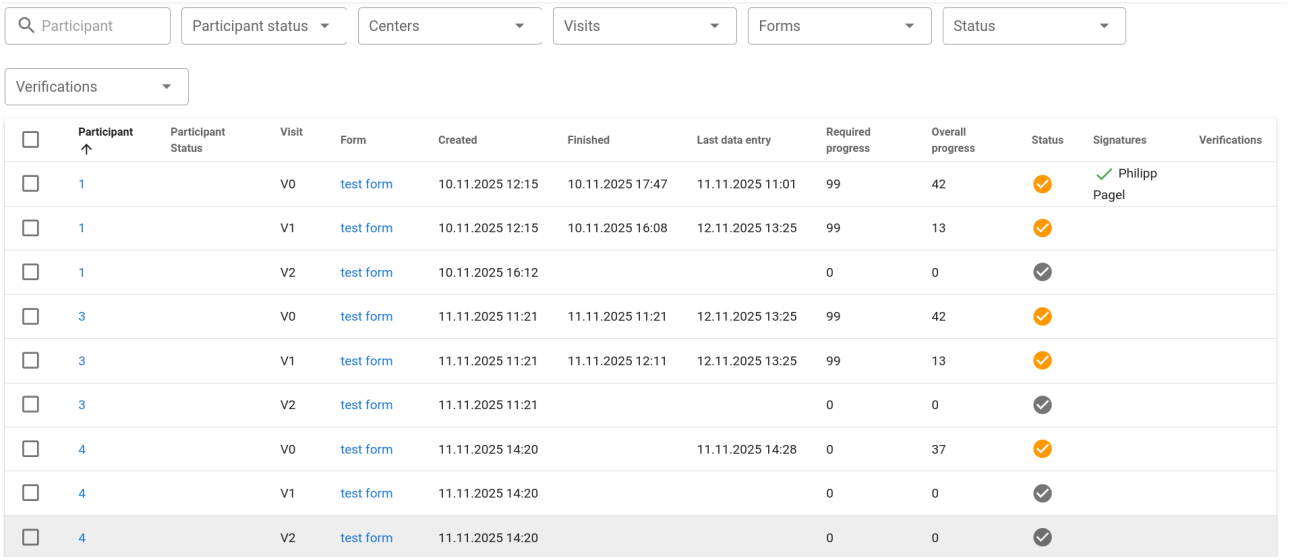
9.8 Source Data Verification (SDV) on question level

You can add SDV indicators to individual questions in the context menu of the question. However, this is only for your own reference. The systems verification list will only show verifications on form-level. So you need to indicate the verification in the *form*-context menu after verifying the individual questions.

SDV is indicated by a green doubletick symbol next to the question.

10 Verification management

Under *Recruiting* > *Verifications* you can get a list of all verifications, signatures etc. in your study.:



The list contains one row per participant, visit and form and there are several columns showing various pieces of information that are useful for monitors and study managers.

It can also be used for bulk operations: Select one or more forms by ticking the box in the first column and select your bulk operation. The operation will be executed on all selected forms.

You can *filter* the list by various criteria at the top of the page. The verification list can also be *sorted* by any of the following criteria by clicking on the respective header. Clicking again will reverse the sorting order:

- Participant ID
- Participant status
- Visit
- Form name
- Form creation date
- Form finish date
- Date of last data entry
- Progress/completeness wrt mandatory questions (percent)
- Overall progress/completeness (percent)
- Form status
- Signatures
- Verifications

Clicking on the participant ID will directly take you to the participant view for the respective patient. Clicking on the form name takes you directly into the verified form of the participant.

The system will remember filter and sorting settings as long as you just click on items in the view and return to the overview using the *Back* button of your browser. Opening other menus in the system and returning to the verification list by clicking *Verifications* in the menu will reset all filters.

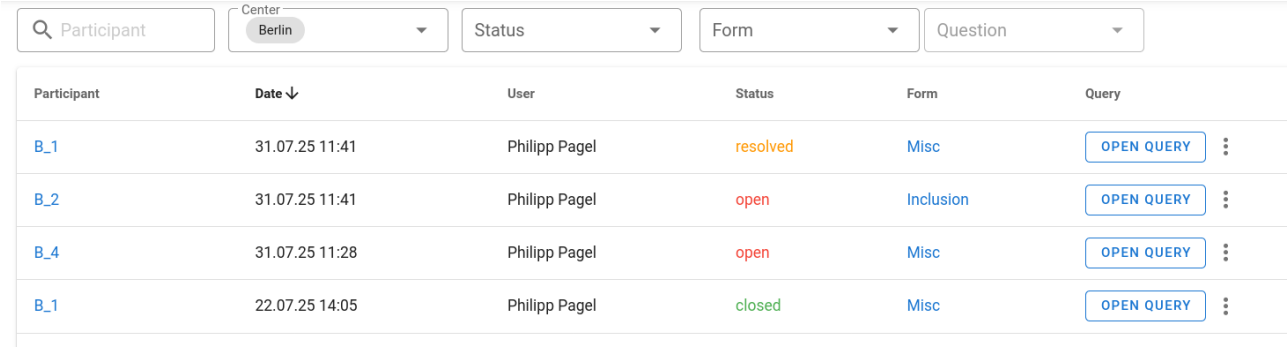
Your role in the study and the permissions associated with it determine what kind of access you have: Verifications can only be set and removed by roles that have the *verify* permission. Anyone with *view* permission can see verifications. Users only have access to verifications in their own center(s).

11 Query Management

In the query management process missing and inconsistent data can be verified by double checking with the respective user and/or participant. The whole process can be executed within the software. So, no additional third party software is needed and the communication between the different parties (e.g. monitor and study nurse) is documented automatically and compliant to GCP in the audit trail.

11.1 Query overview

You can access an overview over all queries by entering *recruiting* > *queries*.



The query list can be *filtered* by multiple criteria including participant ID, center, query status, form, question.

The Query list can be *sorted* by any of the following criteria by clicking on the respective header. Clicking again will reverse the sorting order.

- Participant ID
- Date
- User (who opened the query) – typically a monitor
- Query status
- Form name

You can open and work on the query by clicking *Open query*. Queries can have following states:

Open A pending query that has been opened but not answered, yet.
Indicator: red speech balloon

Resolved Query which has been answered by a site-user but hasn't been closed by the responsible person (e.g. monitor), yet.
Indicator: orange speech balloon

Closed The query has been closed by a user with appropriate permissions thus accepting the resolution given by the site user.
Indicator: green speech balloon

Clicking on the participant ID will directly take you to the participant view for the respective patient. Clicking on the form name takes you directly into the form of the participant containing the query.

The system will remember filter and sorting settings as long as you just click on items in the view and return to the overview using the *Back* button of your browser. Opening other menus in the system and returning to the query list bay clicking *Queries* in the menu will reset all filters.

Your role in the study and the permissions associated with it determine what kind of access you have to queries: Queries can only be opened and closed by roles that have the *query* permission. In order to answer/resolve a query, you need the *edit* permission. Anyone with *view* permission can read queries. Users only have access to queries in their own center(s).

11.2 Opening a query

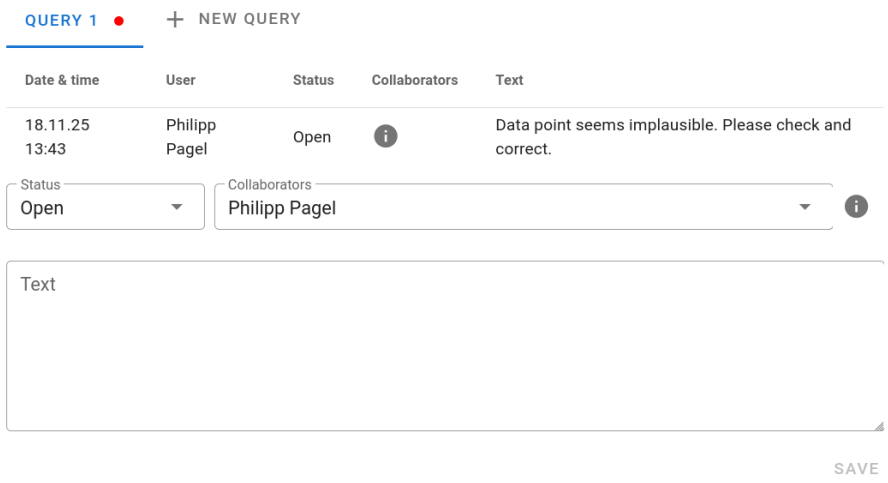
Queries can be opened directly in the respective form:

- Open the context menu (three dots) of the question you want to raise a query for.
- Select *Queries*
- Explain the problem – i.e. content of your query.
- Click *save*

By default, you will be automatically added to the list of people receiving email-notifications when the query changes status (*Collaborators*). In order to add other people, select them from the drop-down menu.

An open query is indicated by a red speech bubble at the right side of the respective question as well as in the participant view.

More than one query can be raised on a data point. In order to add a new query instead of editing an existing query, select + *New Query*. This will create a separate query that can be edited in its own tab.



11.3 Answering/Resolving a query

To resolve a query, first correct the data, if appropriate, then open the query from the participant form or query overview.

- Change the status to *resolved*
- Explain your resolution in the text box
- Click *Save*

11.4 Closing a query

To close a query, open it from the participant form or query overview.

- Review the answer text added during resolution as well as the (corrected) data.
- Change the status to *resolved*
- Comment in the text box. (E.g. “OK”)
- Click *Save*

12 Data exploration

The software offers a simple way of exploring basic properties of your data set. Under *data & analysis* → *data exploration*, you can select a form of interest and explore the different variables of the form. For each question, there is a tabular or graphical representation of the data collected so far.

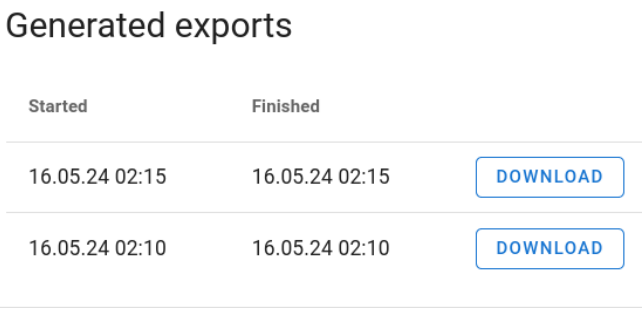
Access to the data exploration requires *export* permissions.

13 Data export

Data export is available at *Data & Analysis* > *Export*. This functionality is only accessible to users who's role includes *Export* permission.

Clicking *Generate* at the bottom of the export screen will generate a zip archive that contains one CSV file for each form or the study, by default. Archive generation can take a while, depending on the size of your study.

Once your export archive is ready, it will appear at the top of the list in the *Generated Exports* box:



Caution: Exports generated by a user will remain accessible in his export list even if permissions change at a later time point. That means that e.g. removing access to a study center or to randomization data will not affect any data the user has exported before the permission change.

13.1 Filtering

Filtering allows you to restrict the scope of the data export. Most of the time, it is advisable to run a full export and handle any filtering in your statistics software, but in some cases, you may wish to apply one of the following filters:

Center Select the study centers to include in the export.

Forms Uncheck *Export all forms* and select the individual forms to include in the export.

Codebook language Select the codebook language to use for the export. Typically, you want to leave this at the *primary language* of your study.

Date If you set a date here, only forms finished *before* this date will be included.

13.2 Options

Format By default, the export will contain one CSV file per form (setting *Separate: files*). If you select *Joint file with prefix*, all individual forms will be combined in one very wide output file. In order to indicate which form a data column originates from, the system will add a *prefix* to each column. These prefixes must be set in the box on the right side of the export screen before starting the export.

You can create separate files for each form or create a joint file which includes all selected forms. If you export the data into one joint file, you will have to set a prefix for each form on the right side of the export screen.

13.3 Additional data

You can tell the system to include one or more of the following pieces of data which are not included by default:

Biosamples Codes and life cycle of registered bio samples

Form PDFs One PDF file per filled form. Also includes metadata such as audit trail, Notes, Queries and verifications.
Selecting this option will slow down export considerably – depending on the number of forms and participants, generating the export can take a few hours. So only select when needed.

Randomization Randomization of participants to study arms. Only available with *View Randomization* permission.
Caution: access to this data will break blinding.

Audit Trail If checked, the export archive will contain two csv files containing the audit trail:
`audit-trail-general.csv` contains the main audit trail, i.e. data entry, data changes, opening form data etc.
`audit-trail-form-structure.csv`: this file contains all events with respect to editing the form structure rather than data. E.g. Adding questions, changing the wording, etc.

Deleted participants You can exclude or include participants who are marked as deleted from the export.

13.4 Exporting the identity log

Users with permissions *export* and *identity* can download the identity log for the study centers they have these permissions for. The identity log is *not* part of the normal export archive, but must be downloaded, separately for each center.

Caution: The identity log contains sensitive personal data and must be handled appropriately to prevent unauthorized access.

13.5 Data Format

The export data comes in a zip archive that contains a number of different files:

```
codebook.xlsx
participants.csv
participants-randomization.csv
study-participant-forms.csv
*.csv
```

The CSV format uses semicolons (';') for column separation and commas as decimal separators(','). These CSV files can easily be imported into all kinds of statistical software, databases, and spreadsheets with the correct configuration.

Caution: While spreadsheet programs like Microsoft Excel or LibreOffice will apparently open these files without a problem, it is **dangerous** to work with data in spreadsheets because these programs will try to infer data types from cell content and silently modify data during import.

Example: If a cell in csv file contains the string 'oct8' which refers to a gene, Excel will assume it's a date and change it to 'october 8th' or '10/8' etc. depending on your format settings. This will breach data integrity!

Here a short description of files present in the export archive:

codebook.xlsx One tab per form. Contains information on the question type, question text, available answers and their assigned variable names and variable coding.

participants.csv Mapping of participant ids to centers and survey identifiers

participants-randomization.csv mapping of participant id and center to randomization result (study arm) as well as time of randomization. Only present if the exporting user has permission *View Randomization* because it breaks blinding.

study-participant-forms.csv Information about lock and delete dates of forms.

joined.csv Present if format *Joint file with prefix* was selected. Each row is an observation. Different forms are joined side by side. So these tables can get very wide. Column prefixes indicate the origin of a column.

audit-trail.general.csv This file contains the main audit trail – views, edits, deletions, permission changes etc.

audit-trail-formstructure.csv This file contains all audit trial events regarding changes to the structure and content of the forms used in the study.

***.csv** One file per form containing all entered data. One row per observation.

Form exports always start with the following columns:

```
participant_identifier
center_name
created_at
started_at
finished_at
visit_name
form_index
diary_date
```

All subsequent columns represent the different questions of each form. If a form is included in multiple visits, these copies result in separate rows in the file. I.e. to uniquely identify a data record, you need to use `participant_identifier`, `center_name` and `visit_name` as a *composite key*. If you have forms that can be added multiple times, you also need to include `form_index` in the composite key. If the form is part of a patient diary, `diary_date` must be added to the key.

The data only includes forms that have at least be opened but not necessarily finished.. Forms that were never opened will not appear in the export.

The time stamps `started_at` and `finished_at` will allow you to discern finished forms from those that have only been started but never finished.

14 Importing data

Importing data can be helpful in case the data is generated externally in bulk. Typical examples include large laboratory test panels that can be provided electronically by the lab or data generated by medical devices. Now, instead of transcribing the data manually, you can import it into the system which is a lot less error prone.

Data can be imported at any time during the recruiting process. You can find the import menu at *Data & Analysis* → *Import*. In order to import data, a few prerequisites must be fulfilled:

1. All target fields you want to import into must exist in a regular form in your study just as for manually entered data.
2. The codebook of all target fields must be filled in – i.e. they have a variable name and variable coding (for some data types).
3. You must have the necessary permissions for the import:
   - *import* permission
   - *edit* permission for all study sites you want to import to
4. The import file adheres to the required format.

14.1 Import Data Format

Import files must be in CSV format using a semicolon (`;`) as a field separator. The first row of the file contains the column headers. There are a few mandatory columns that are needed to correctly identify the participant, visit and form for the data.

Column	Description
`participant_identifier`	participant identifier as configured for your study. E.g. `B_57`, `00207` or `C1_XL3J5SD`
`center_name`	Name of the study center
`visit_name`	Name of the visit
`finished_at`	Optional: if set to an ISO date or datetime, the form(s) you import into will be set to `finished`, otherwise they remain in their current state (probably `started`)
`diary_date`	Only for participant diaries: date of the entry
`form_index`	Only for *added* forms. Numerical index (1, 2, …)

All columns that follow these required columns must use the correct variable name in the header row and the correct data format in the data rows. **Do not leave data fields empty** – the behavior of the importer with respect to empty fields is officially undefined and may change in the future.

Caution: Dates must be given in ISO-8601 format (`YYYY-MM-DD`, e.g. `2024-10-12`) or as datetimes using universal time (`YYYY-MM-DDThh:mm:ss.sssZ`, e.g. `2024-10-12T09:33:55.151Z`).

You can download file templates of your forms in the import dialog. The first row of these templates contain all required columns and all data fields of the form with a valid codebook entry. The second and third

row in the template are for your information and contain the original question text and the expected data format of the respective columns, respectively. These to rows must be removed before upload. You can just copy&paste your data into these templates and then upload them.

You can combine data from different forms in the same import file – the system uses the variable names in the header row to identify the location of the data field.

Importing data will not set the respective forms to *finished*, by default. If you want that to happen, you need to include a column named `finished_at` and provide a date or datetime in it. The importer will then set all forms to *finished* that it imports data into.

14.2 Starting the import

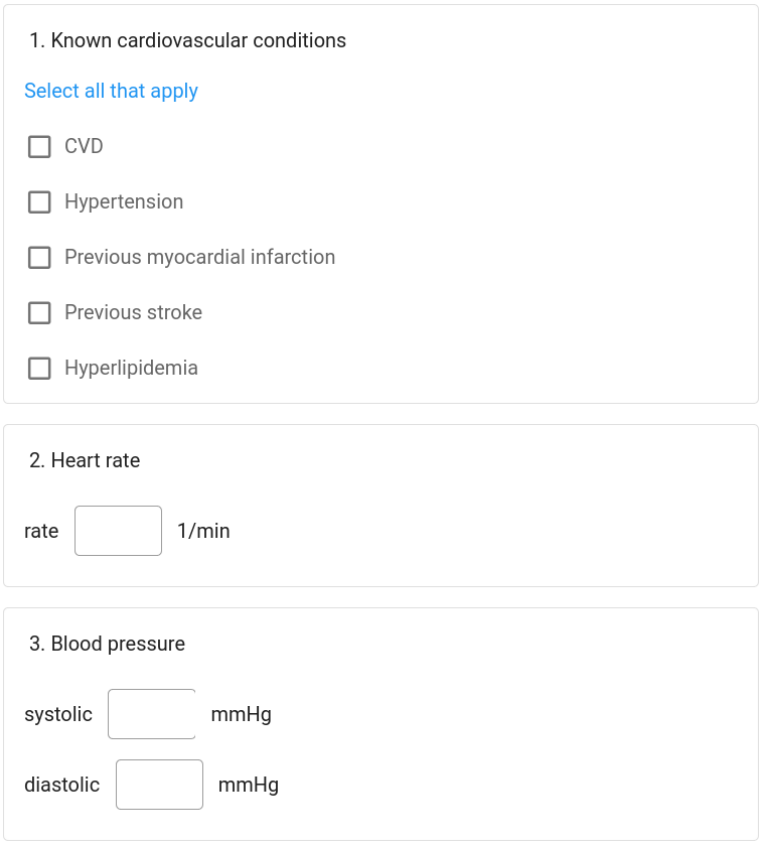
Once your data file is ready, go to *data & analysis* → *Import* and click the *Upload* button. Select your import file in the file selection form and press *OK*. The system will check uploaded files and show error messages if it cannot find a variable name or encounters incorrect data formats or data coding. If the pre-check passes, you will be shown a preview table that indicated all changes the system will make upon import. If you select *Import*, The import starts.

By default, you can only import data into *existing participants* and get an error message if the importer encounters a non-existing participant identifier. However, if you select *Create missing participants* in the import dialog, the system will automatically create a new participant when an unused id is found.

Import actions are documented in the audit trail under the name of the user starting the import.

14.3 Example

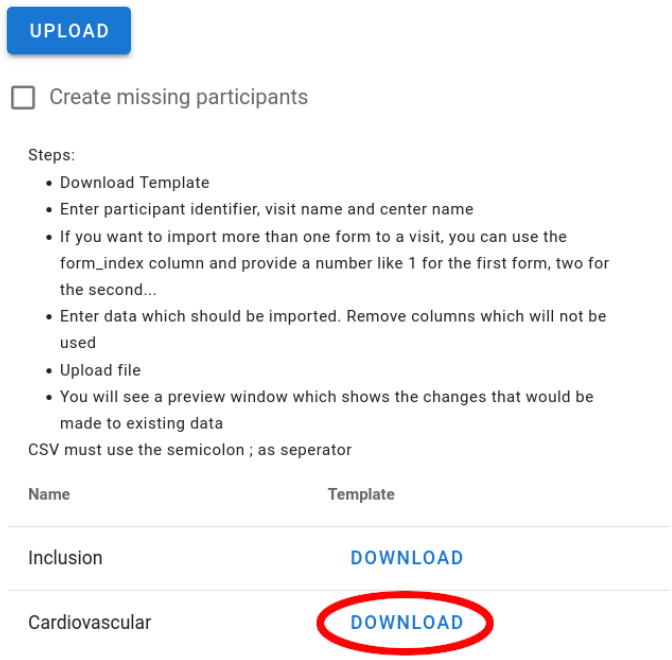
LEt's say we have a small form covering some cardiovascular parameters:



If we want to import all data into this form, we first fill in the codebook:

Question	Field	variable name
Q1 Cardiovascular conditions	CVD	`cvd`
	Hypertension	`hypertension`
	Myocardial Infarction	`MI`
	Stroke	`stroke`
	Hyperlipidemia	`hyperlip`
Q2 Heart rate	rate	`heartrate`
Q3 Blood pressure	systolic	`rr_sys`
	diastolic	`rr_dia`

Now we can go to the *Import* menu and download the template for this form:



The resulting CSV file contains the standard columns described above and all your data columns as defined by the codebook variables. For the Multiple-Choice question options, you will get the full text and the variable coding in rows 2 and 3. E.g.:

```
cvd
Known cardiovascular conditions
1 = CVD, 0 = not checked
```

or

```
hypertension
Known cardiovascular conditions
1 = Hypertension, 0 = not checked
```

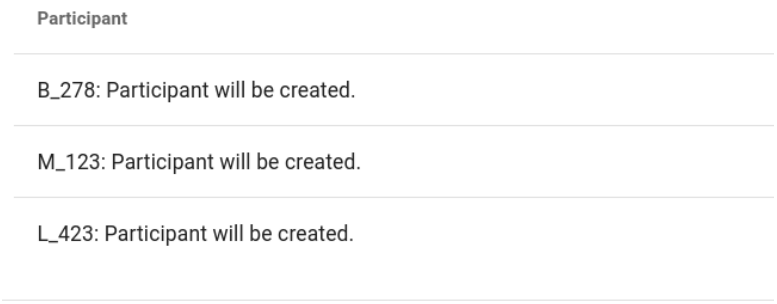
For the numeric fields, the hint is simple:

```
heartrate
Heart rate
rate = number
```

So now we know how to fill in the table. E.g.:

participant_identifier	visit_name	center_name	...	stroke	hyperlip	heartrate	rr_sys	rr_dia
B_378	Inclusion	Berlin	...	1	0	72	140	95
M_123	Inclusion	Munich	...	0	0	61	130	85
L_423	Inclusion	London	...	0	1	68	160	90

Save the file in CSV format (with semicolon separators) and you can now import it by clicking the *Upload button* on the import page. If you selected *Create missing participants*, they are generated automatically and the preview window will tell you so:



After the import, the new participants are now available and the respective form contains all data from the file.

15 Randomization

Most clinical studies, and in particular the canonical *randomized controlled trial* use randomization – i.e. randomly assigning study participants to one of at least two *groups* or *study arms*. While this can be done manually, it is much more convenient to have the software handle the randomization process

Our software supports this by accepting externally prepared *randomization lists* that define the available randomization slots. All randomization functionality is provided by the *randomization module* that can be booked for your study.

15.1 Randomization permissions

Randomizing a participant is possible for roles that have the *randomize* permission. Users in such roles can trigger randomization for study participants associated with their study center(s).

The *View randomization* permission, on the other hand, allows users to see which study arm (*group*) a particular participant has been randomized to. Users/roles with this permission will *not be blinded* with respect to randomization. Accordingly, great care should be taken in deciding who shall receive that permission.

Finally, someone needs to upload/manage randomization lists in the system. All users with the top-level permission *Study general settings and go-live* have the ability to do that. Randomization lists that are *down*loaded at some point when the study is running contain information about slots that have been assigned, already. While the list does not show participant IDs, it is not sufficient for unblinding, but it does contain information that conveys information about randomization status of existing participants. Accordingly, this permission should be given to a small, selected group of users, only.

15.2 Randomization lists

Our software uses pre-generated randomization lists that are provided by study admins and then used to assign a slot in the list and the respective *group* (= study arm / sub-cohort/ ...) to participants. In the following sections we will explore some common randomization schemes and how they can be set up.

Randomization setup is located at `Setup > general > randomization`

Randomization lists need to be in CSV format (using semicolons as field separators and commas for decimal separator). The first row defines the column names, all other rows are data. Each data row in the list represents one *slot* that is available to a participant. So if you want to recruit 50 participants, the randomization list must contain at least 50 *slots* (rows). Once all slots have been used/assigned, no additional participants can be randomized.

We recommend to start by downloading a randomization list template. The resulting CSV file shows the expected format, required columns as well as some examples for optional columns. The download link is located in the introductory text in the randomization section f the setup.

Upon randomization, the system will assign the participant to the first unused and matching slot. Therefore, row order in the list determines randomization order. Randomization lists ensure that you can have full control over the size of the total cohort as well as the sub-cohorts (groups).

15.2.1 Simple randomization

Simple randomization means that participants are randomly assigned to groups with a certain probability – much like tossing a coin or throwing dice. You can define as many *groups* as desired. The probability for each group is defined by the proportion of slots for the group in the list.

So if you want to recruit 100 participants and allocate them in a 60/40 ratio to the two groups *Drug* and *Placebo*, you need to create a list with 60 rows for group *Drug* and 40 rows with group *Placebo*.

For a study with 90 participants equally distributed over three groups *A*, *B* and *C*, the lists must have 90 data rows – 30 for each group.

The randomization list for simple randomization requires only one single column *group*. Creating a simple randomization list is easy:

- Create a csv file with one column header: *group*.
- Add as many rows for each group as you need for the desired ratio and cohort size.
- Randomly shuffle the order of the data rows.

15.2.2 Block randomization

Simple randomization ensures that at the end of recruitment, the study cohort has the desired group sizes and ratio. However, group ratios can vary substantially over the course of recruitment. Block randomization is a popular method to ensuring that group ratios remain close to the desired values over the entire course of recruitment.

Explaining the exact method for creating a block-randomization list is beyond the scope of this manual and can be found in the statistical literature. Briefly, the process is this:

- Decide on number and ratio of groups
- Decide on suitable block size *k*
- Create blocks of size *k* that contain permutations of your groups.
- The number of blocks is determined by the desired cohort size as well as block size.

Common statistical software systems such as SAS or R offer tools for generating block-randomization lists.

15.2.3 Randomizing by study site (center)

When a single randomization list is applied to a multi-center study, there is no control over the individual center's contribution to the study groups. If you want to ensure that group balance is also maintained within the individual centers, you need to randomize stratified by center. The easiest way to do that is to include a *center* column in your randomization list. Upon randomization, the system will then find the first free slot for the respective center.

Alternatively, you can upload separate randomization lists for each center.

The system will allow mixing of global and per-center lists. In that case, the system uses center-specific lists before falling back on the global list(s) in case not free slot is found in the former. This may be useful in certain situations but should not be used in most normal settings.

15.2.4 Stratified randomization

Sometimes, it is desirable to keep a certain balance of known covariates within each group. Common examples include *sex* or *age group*. This can be accomplished easily:

First, you need to make sure that the relevant variables are included in a form and that this form is included early in the study so that the data is available at the time of randomization. Stratified randomization only works with categorical variables – typically implemented as single-choice questions like "Sex: male/female".

In order to allow stratification by these questions, you need to assign an *alias* to the respective questions (e.g. `$sex`) and include the alias as a column in your randomization list. The resulting list then looks something like this:

```
group   $sex
A       m
B       f
A       f
B       m
[...]
```

You can include multiple aliases for stratification. E.g.:

```
group   $sex    $age_group
A       m       18_30
B       f       18_30
A       f       18_30
B       m       18_30
A       m       31_45
B       f       31_45
A       f       31_45
B       m       31_45
[...]
```

The stratification aliases should be categorical – i.e. single-choice questions. If you know what you are doing, computed fields also work, but make sure you fully understand what the possible return values are.

15.2.5 Crossover designs

Some studies implement a crossover design. E.g. participants who were randomized to group *A* are treated with the drug under test over the course of the first visits while group *B* receives a placebo. After finishing a certain visit, the participants are then switched to the opposite group so that all participants receive both treatments at some point during the trial.

Although our software has no specific feature to switch group assignment, it is easy to implement crossover designs by using slightly adapted group definitions. Instead of defining Group *A* as "Drug" and *B* as "Placebo", you should define *A* as "Drug then Placebo" and *B* as "Placebo then drug".

15.2.6 Appending to the randomization list

Sometimes things don't go according to plan. For example, you may need to recruit more participants than planned, initially. So you will have to extend the randomization list to do that in a running study. While you cannot directly append rows to an existing list, you can easily upload another one of the same format. The system will treat additional lists as extensions and will move to the next list once the previous one is exhausted.

15.2.7 Downloading the list

Randomization lists that are already in use by the system can be downloaded by users with *setup* permission. The downloaded list has gained additional columns that were appended by the system:

column	type	Description
`used`	true/false	`true` if the slot has been allotted to a participant, `false` otherwise
`created_at`	timestamp	Creation time of the slot
`created_by`	email	user who uploaded the list
`deleted_at`	timestamp	time of deletion, empty otherwise
`deleted_by`	timestamp	user who deleted the slot

15.2.8 Deleting lists

It is possible to delete lists from the system. However, lists will only be fully deleted if none of their slots has been used at the time of deletion. Any slots that are already in use cannot be deleted once the study is live.

15.3 Randomization workflow

In the participant view, a *Randomization* widget will be displayed. Clicking *Randomize* will initiate the randomization process and after confirmation, the system will search for an available slot that matches all stratification criteria, starting from the top of the list.

User with *view randomization* permission will be able to see the group/arm a participant has been randomized to.

Both triggering randomization and looking up the result are recorded in the audit trail. Please note, that randomizing a participant is an *irreversible* event. I.e. you cannot undo the randomization once it has been done.

15.4 Emergency unblinding

Especially in drug trials, it may become necessary to break blinding of the site personnel with respect to the study arm a participant is in, so that appropriate treatment can be administered in an emergency.

This can be achieved by making sure, that accounts with *view randomization* permissions are available at the sites but not used during normal work. Access data for these accounts may be kept in sealed envelopes or kept by previously designated people.

15.5 Special Alias

You can access the randomization result in computed fields and visibility rules via the special alias `$_randomization_group`.

Caution! This feature has the potential to break blinding! Only use after careful consideration.

15.6 FAQ

Q: I want to control the group probability but not the exact size of my sub-cohorts. Can that be done?

A: Yes. Just make sure you randomization list contains many more slots (rows) than you will need. That way, you can set the desired group ratio but nor exact group size.

Q: Can I use the result of a computed field for stratified randomization?

A: Yes, you can. Just make sure there is an alias for the computed field and that it returns the desired categories.

16 API access

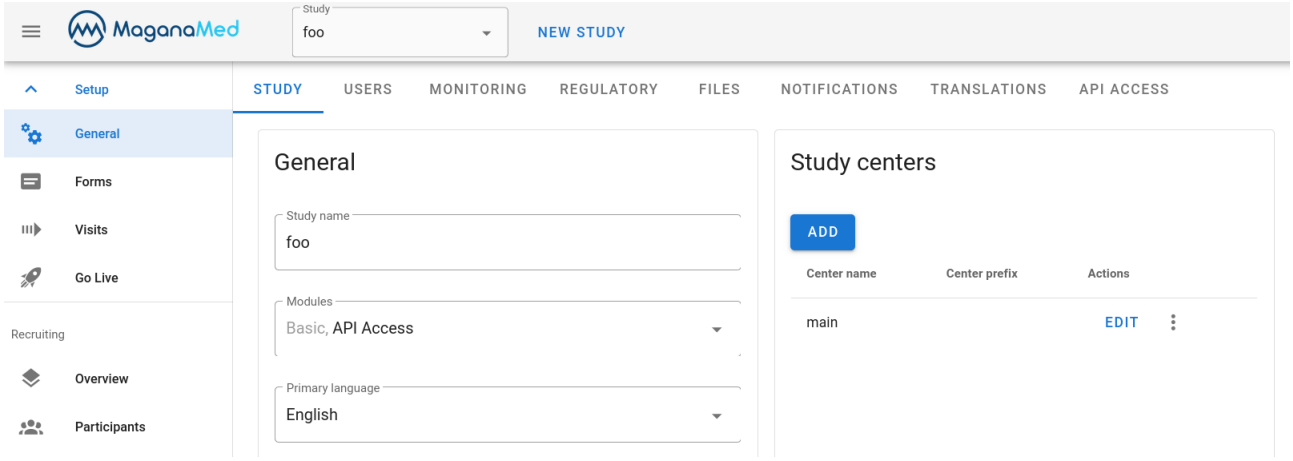
The API is our *Application Programming Interface* available to customers. The API allows accessing selected data and functionality of your study by external software – e.g. collecting heart rate from a smartwatch, sending data from a medical smartphone app, developing external data import scripts or for targeted data downloads for data analysis.

16.1 Setup

In order to allow API-access, the following steps must be taken to activate the respective module and create an authentication token.

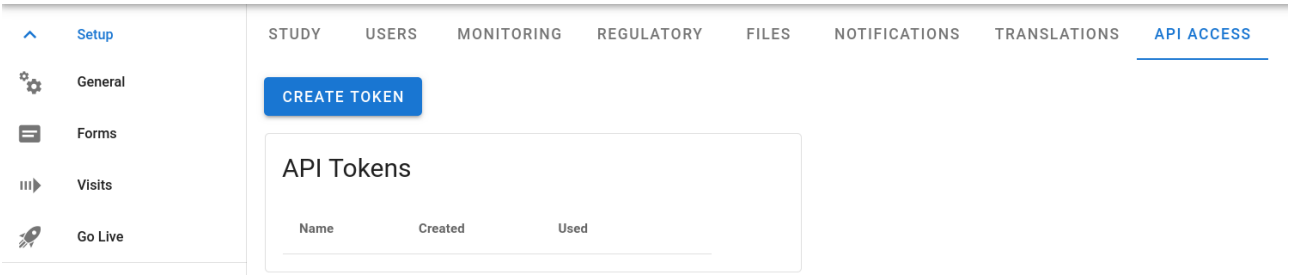
Activating the API-Access module

- Open your Study.
- Go to *Setup* > *General*
- In the *Study* tab open the *Modules* menu and check the *API Access* module



Generating an API authentication token

- Under *Setup* > *General*, open the tab *API token*.
- Click on *Create token*.
- Enter a descriptive name for your token. Access using the token will appear in the audit trail under the name of the token. Typically, the name of the application using the token makes a good token name.
- Click *Create token* and store the token immediately. It will only displayed once at the time of creation.



Delete an existing API authentication token

Deleting a previously created token is possible in the same menu where it was created. Just click the `X` symbol and confirm the deletion by clicking *yes*.

Caution: Token deletion is irreversible. To re-grant access, a new token must be created and used by the application.

16.2 Security

Caution: API access is very powerful! Unlike a normal user, applications using the API are **not restricted** by user roles or centers but have full access to everything that the API implements across the entire study. Applications using the API are responsible for maintaining any separations required, e.g. center separation, user authentication, access to or blinding of randomisation data, etc.

Never rely on the fact that something is not accessible through the API at the time of implementation of your application. Future extensions of the API will further augment the breadth of access – even for previously created tokens and applications. So you should assume that the API offers access to everything.

Authentication tokens must be kept secure at all times and we urge API users to follow these rules:

- Rotate your API token regularly, at least annually.
- Never embed authentication tokens directly in your front end applications (iOS, Android, or HTML).
- Always store API tokens securely within your back end environment.
- Ensure that authentication tokens do not get committed to code repositories, private or public.

16.3 Functionality

At the moment the API supports a small set of common tasks.

- get a list of centers (study sites)
- get participants and their visits and forms, including data
- Write data to participant forms
- Create and delete participants

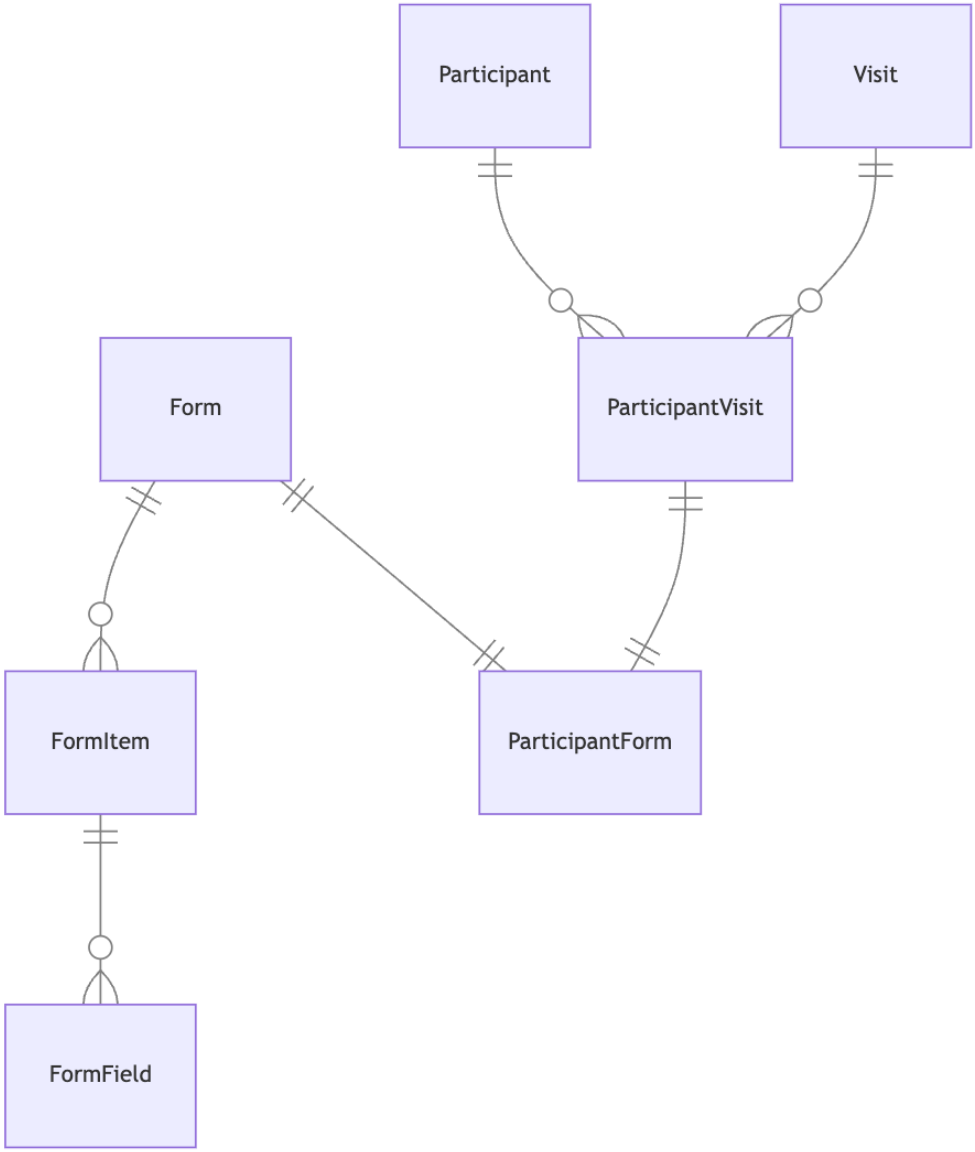
If you need additional functionality, please get in touch with us.

16.4 OpenAPI Specifications

For details on available API functionalities, refer to the OpenAPI specification located at: https://public-api.maganatrial.com/documentation/

API tokens can be submitted by clicking on the green *authorize* button.

16.5 Entity structure



- `Form`: Represents a form that collects data from participants.
- `FormItem`: Represents an item within a form, such as a question or text.
- `FormField`: Represents the type of data that a form item can hold, such as text, date, or checkbox.
- `Participant`: Represents an individual who is part of the study.
- `ParticipantVisit`: Represents an instance of a visit which is part of a participant.
- `ParticipantForm`: Represents the association between a participant and a form, indicating which forms a participant has filled out.
- `Visit`: Represents a study visit.

16.6 Data types

Form fields can have the following types:

- `singleChoice`: Encoded with `true` for checked fields.
- `multipleChoice`: Encoded with `true` for checked fields.
- `date`: Encoded as string in ISO 8601 format (`YYYY-MM-DD`.
- `time`: Encoded as string in 24h format (`HH:MM`).
- `textarea`: Encoded as string.
- `number`: Encoded as number e.g. `1.5` or `2`.

16.7 File uploads

- To upload files through the API, you need to set the `content-type` header to `multipart/form-data`.
- You can access uploaded files directly using the static url provided in the response. Don't forget to include your API Token in the Authorization header for authentication.

Example: `https://public-api.maganatrial.com/v1/static/participants/157/uuid.png`

16.8 Visibility, validations and computed fields

When retrieving a participant form, the API evaluates visibility, validations, and computed fields and includes them in the response. However, in some situations, it might be necessary to assess visibility and validation locally without sending data to the backend. To accommodate this, the forms endpoint provides a `visibility` and `validation` object for questions with visibility or validation rules. If the `advanced` entry is set to `false`, you can evaluate these rules directly in the frontend. Note that a number field with a value of `0` is considered an answer and should trigger the display of related questions.

16.9 Rate limiting

Currently, our API doesn't have strict rate limits in place. We trust our users to use our services responsibly. However, we monitor API usage closely. Excessive or abusive usage may lead to API key revocation without warning. This is to ensure fair access for all users.

The endpoint `GET /v1/participant-forms/{id}` is an exception. Excessive requests for the same form will be blocked. This is because we log access to the form data and track access for audit purposes. To avoid unnecessary audit entries, please use `GET /v1/participants/{id}/visits` to check if the form data has changed before requesting it.

16.10 Examples

16.10.1 Creating a participant and entering data

Preparation

- Create a new study.
- Enable module *API Access* and create a token.

- Create a new form and drag a single choice question into the form.
- Create a new visit, click on edit and add the previously created form.

Example Script

Execute the following script and provide the token as environment variable. After executing the script, open the created participant and verify if the first option in the form is selected.

```python
#!/bin/env python3
import os, json, requests

base = "https://public-api.maganatrial.com/v1"

# get authentication token from ENV
# do NOT hardcode it!!
bearer_token = os.environ["TOKEN"]

headers = {
    "Authorization": f"Bearer {bearer_token}",
    "Content-Type": "application/json",
}

# get list of centers/study sites
centers = requests.get(f"{base}/study-centers", headers=headers).json()

# create a new participant
participant = requests.post(
    f"{base}/participants",
    data=json.dumps({"centerId": centers[0]["id"], "identifier": ""}),
    headers=headers,
).json()

# get all visits of the new participant
visit = requests.get(
    f"{base}/participants/{participant['id']}/visits", headers=headers
).json()

# get the first form in the first visit
participant_form = visit[0]["participantForms"][0]
form_id = participant_form["form"]["id"]
participant_form_id = participant_form["id"]

# get form structure
form = requests.get(f"{base}/forms/{form_id}", headers=headers).json()
item = form["items"][0]
field = item["fields"][0]

# import data
data = {"formItemId": item.get("id"), "fields": {}}
data["fields"][field["id"]] = True
response = requests.post(
    f"{base}/participant-forms/{participant_form_id}",
    data=json.dumps({"items": [data]}),
```

```
    headers=headers,
)
```

Terms and Abbreviations

2FA Two-factor authentication. A form of Multifactor Authentication. Method that adds an additional fator to traditional password authentication.
Account Basis to use the software more than just filling in a assigned survey
AES Advanced encryption standard
API Application Programming Interface. A well defined set of methods throiugh wich external software can exchange data with Magana Trial Manager
Center Study center, study site. Location at which a traditional study *visit* is conducted. Typically, a hospital, clinic, doctors office or lab.
CFR Code of federal regulation. Important part of federal law in the USA.
CRF Case report form
eCRF electronic case report form
EDC Electronic data capture
Form Individual form in a study. Part of the entire CRF.
GCP Good clinical practice
GDPR General data protection regulation
GUI Graphical user interface
MFA Multifactor authentication. See 2FA.
Participant Person enrolled in the clinical trial, typically a patient. Sometimes referred to as *patient* or *subject*.
Permission Technical setting in the system that defines what a user can do or access. Important tool for implementing data parsimony (*need to know* principle).
Role Prototypical type of user with specific tasks and responsibilities. Defined by a specific set of permissions in the system that are required to fulfil their duties.
SaaS Software as a service.
SDV Source data verification
TOTP Time-based one-time password. A common method for multifactor authentication
TLS Transport layer security
URL Uniform resource locator (web address)
User Person uses the software
Visit Touching point with participant to obtain clinical data

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