The Intensive Care Platform Trial (INCEPT)

Guideline for Data Entry

Guideline for Data Entry version and date
Version 1.0, 2025.06.12
Website
www.incept.dk

Applicable protocol registration numbers
CTIS EUCT number: 2024-516208-41-00
ClinicalTrials.gov identifier: NCT06667999
Universal Trial Number: U1111-1313-8171

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Content

This is a brief manual to the overall use of the eCRF of INCEPT. For more details, please refer to the actual EasyRF User Manual.

1. Login

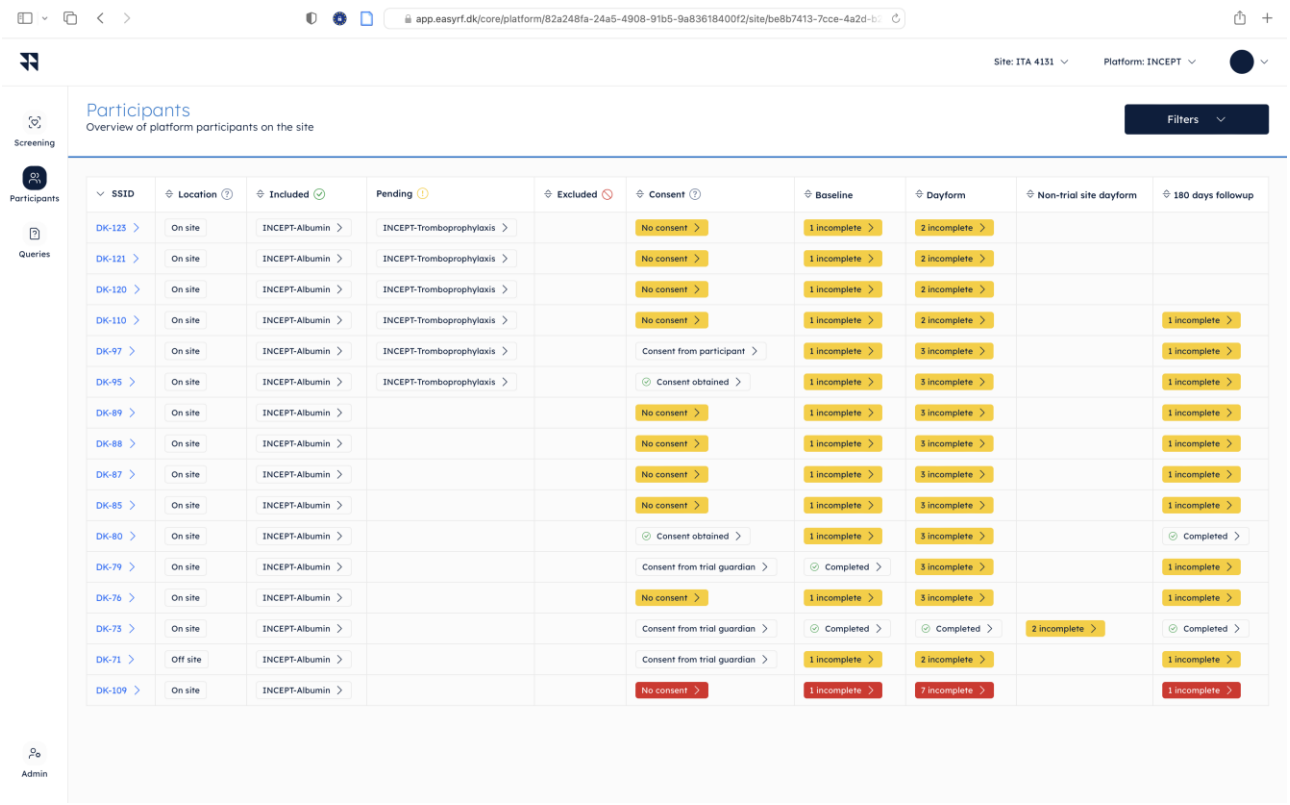
Logging in requires so-called 2-factor authentication (2FA), meaning that you enter your username (or email) and password. If those are correct, you must then enter a so-called one-time password (OTP). Currently, there are two ways to get the OTP: via an authenticator app (e.g. from Google or Microsoft) or via email. The first time you log in, you must choose the method and set it up. If you forgot your password, simply click "Reset password" and follow the process from there to make a new one.

If the system is unavailable, please check again later and contact the technical support if the problem persists.

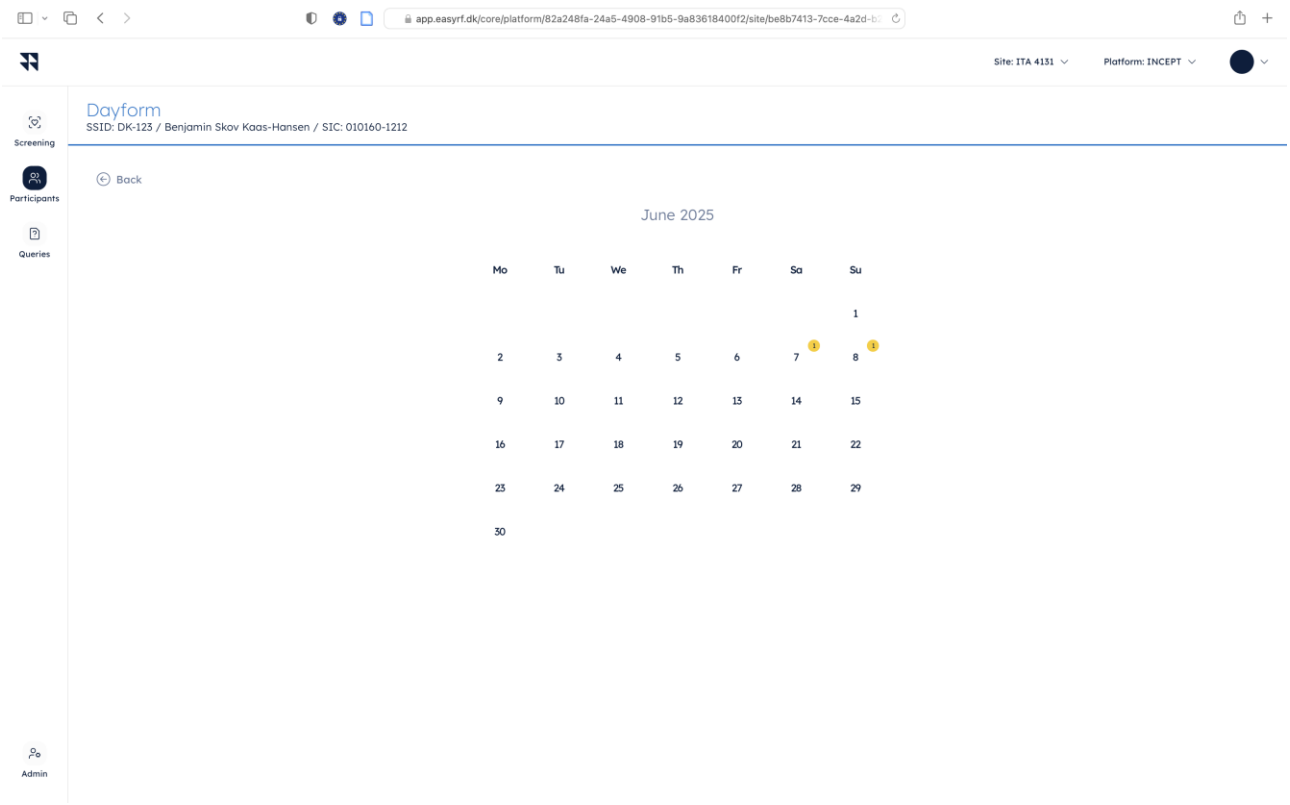
2. Data entry and correction

Observations are one of the two main pillars in EasyRF. By observation, we mean the value of a variable in a subject within a given timespan recorded by a specific role type. For a day form, the timespan is usually 24 hours except for the first day form, while the timespan for a baseline form might be 0 hours. This is important because it determines how observations can be shared across forms, domains and even platforms: if two domains use a variable called, say, “Most recent p-lactate” in their baseline forms, and a subject is enrolled in both domains are the same time, the eCRF will have only a single observation—but linked to both forms and, by extension, to both domains. This way, the observed value is entered, seen and saves in one place.

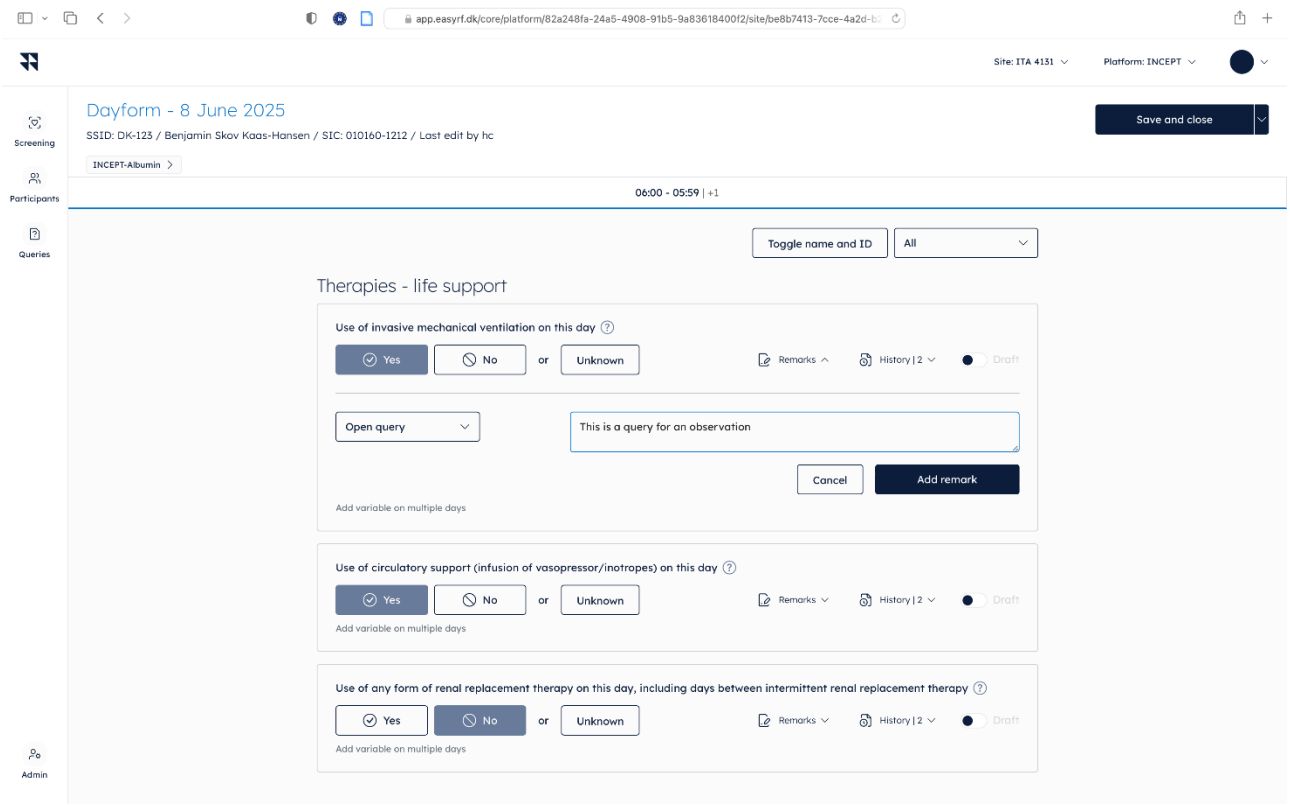
Data entry happens via forms that are accessible from the Participants overview and divided into form types. This example has four form types: baseline, dayform, non-trial site dayform and 180-day follow-up:



Clicking on a button in e.g. the dayform column will take you to the actual form if there is only a single day or, otherwise, bring up a calendar with days on which there are forms. Green circles denote complete forms, yellow circles incomplete forms, and red circles incomplete forms that should be prioritised:

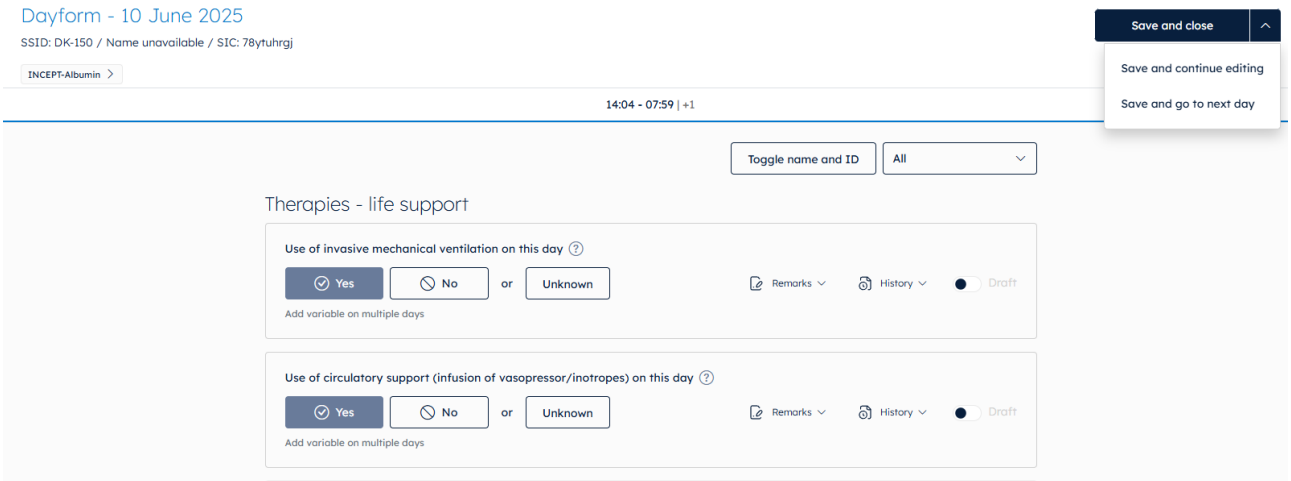


Click on the day for which you want to fill out the form(s) and you will be taken to something along the lines of this:

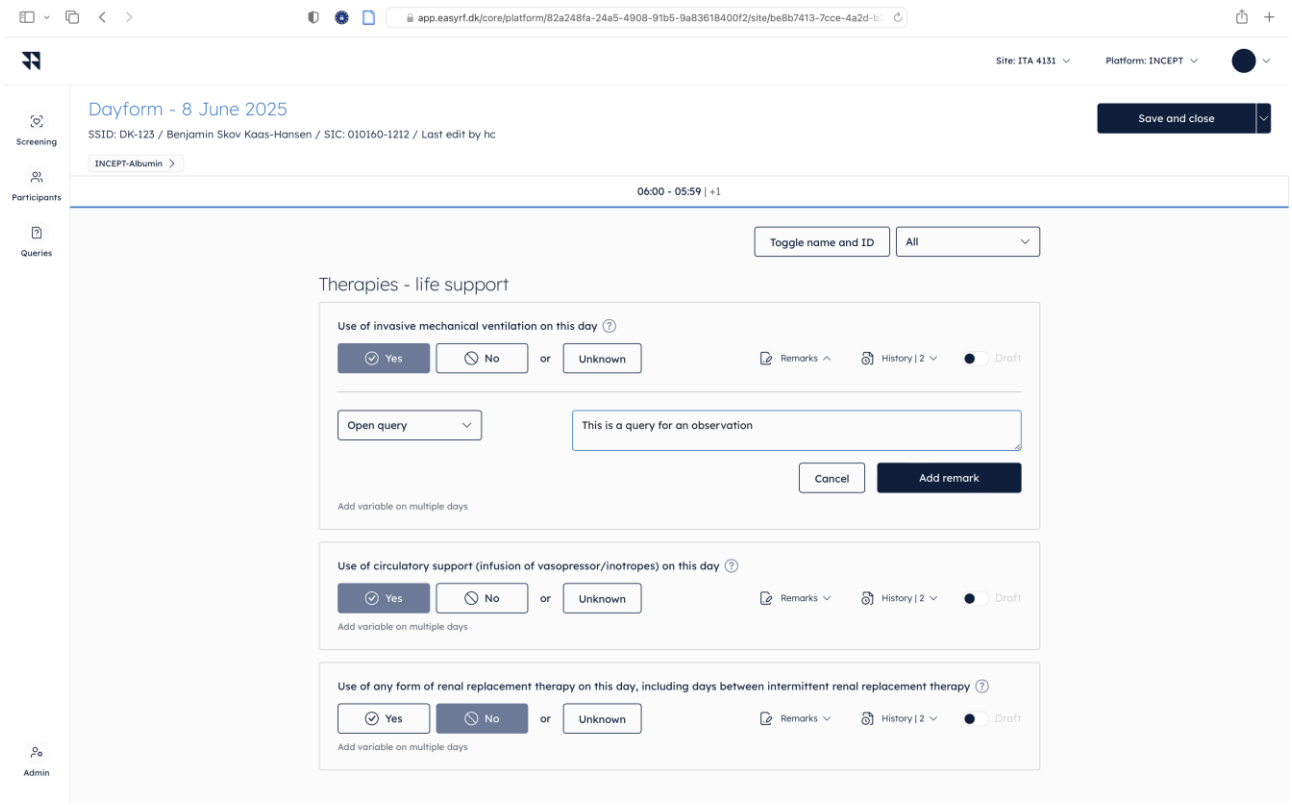


Each tab contains observations for the timespan of the tab. |+1 means that the time is on the next calendar day so 6:00-5:59|+1 means that the observation covers the time span between 8 June at 6:00 in the morning and 9 June at 5:59 in the morning.

Enter the data you have available and save. Saving has three flavours, and if you do not want to close the form after saving, choose one of the other options in the drop-down:



Clicking Remarks will open all remarks for the observation in question and let you add remarks directly there:



As you see, queries are just a particular type of remark and one that can only be added by monitors and site investigators.

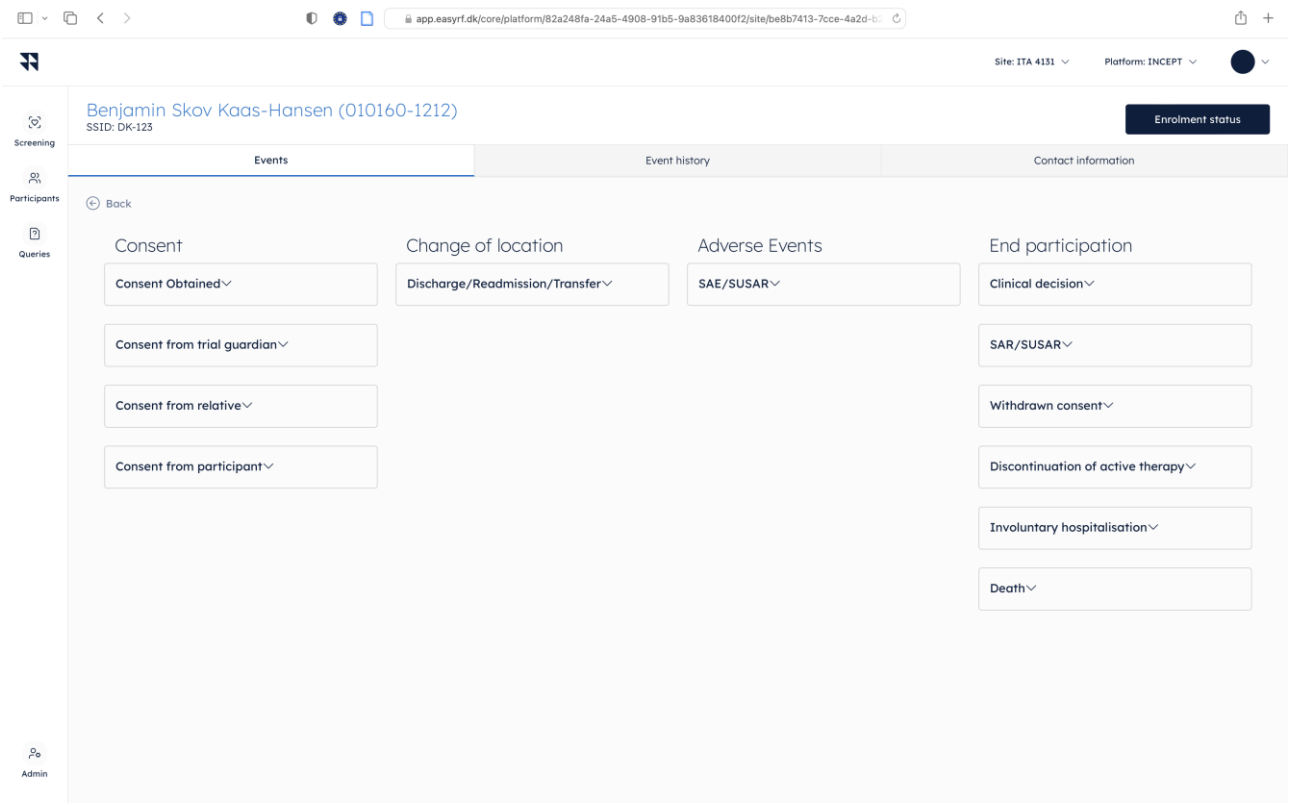
Correction of observations follow the same workflow as entering new data. If you want, you can motivate the change in a remark, but that is not a requirement. The full audit trail of each observation is available by clicking History, which will show all previous values, when they were added/edited and by whom.

If you click on the domain name in the Included or Excluded columns in the Participants overview, you are taken to the appropriate screening form. This is only editable by site investigators but visible to all users with access to forms; notice how fields are dimmed if your user is not allowed to change their values.

While the screening form observations can be changed by site investigators, there is no way for users to change the actual allocation of the participant. If that needs to happen, the site investigator must contact the technical support, which can help with this. If a person is enrolled by mistake, it is enough to end participation on the Participant detail page choosing the appropriate reason.

3. Events

The other main pillar in is Events. Events are, essentially, anything that happens to a subject as part of their participation in the trial is an event. The very first events are platform and domain enrolments but attempts at obtaining consent are other events just as ending participation prematurely. Events and their metadata are added om the Participant detail page, and to get there you simply click on the ID in the left-most column in the Participants overview. For most users, there will be three tabs: Events, Event history and Contact information:

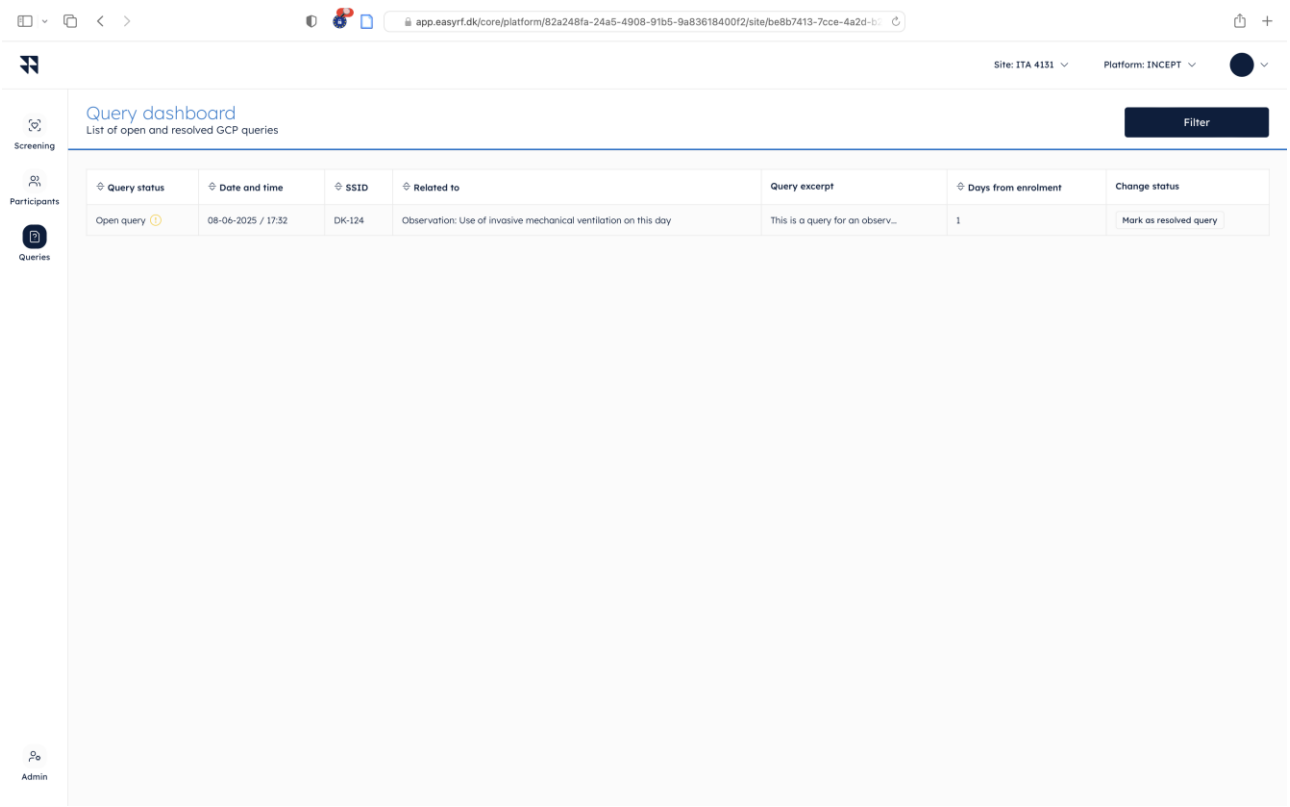


The most common events will likely be related to the different stages of the consent process, changing the location of participants and end of participation, e.g., death.

Adding some events, such as a SUSAR, will trigger the creation of specific forms, while others will not. Changing location of the participant may close some forms and open others: for example, transferring the participant to a non-trial general department will inactivate the very detailed day forms but activate shorter, simpler forms collecting data on variables that are needed for the capture of outcomes.
Under Event history, you can add remarks to existing events. Just as for observations, monitors can open queries against events, and these will be shown in the Queries overview.

4. Queries

As described above, monitors can raise queries by creating an Open query remark for an observation or an event. Although all users with access to data entry can see queries, only site investigators and monitors can close queries. All queries show up in the Queries page:



Users may change the status on the right-most corner. Clicking on the row of each query will take you to the observation question or event.