MediCase database

- Web browser
- How to register a user and a case in MediCase
- General principles
- eCRFs in MediCase
- When more than one site is involved in a case
- Retrospective data input

Web browser compatibility

MediCase is compatible with most modern web browsers, including updated versions of **Chrome, Safari, Firefox and Edge**.

It is supposed to be compatible also with Internet Explorer but some users may experience minor problems using Internet Explorer in certain environments.

Since Internet Explorer is no longer supported by Microsoft we recommend not to use it with MediCase.

Register in MediCase FASSprosp

New user

- Send an e-mail to the study PI/coordinator
- Receive invitation e-mail and reply

Registered user

- A case can be registered if there is a diagnosis of fetal aortic stenosis and inclusion criteria are fulfilled between 23+0 and 31+6 GW.

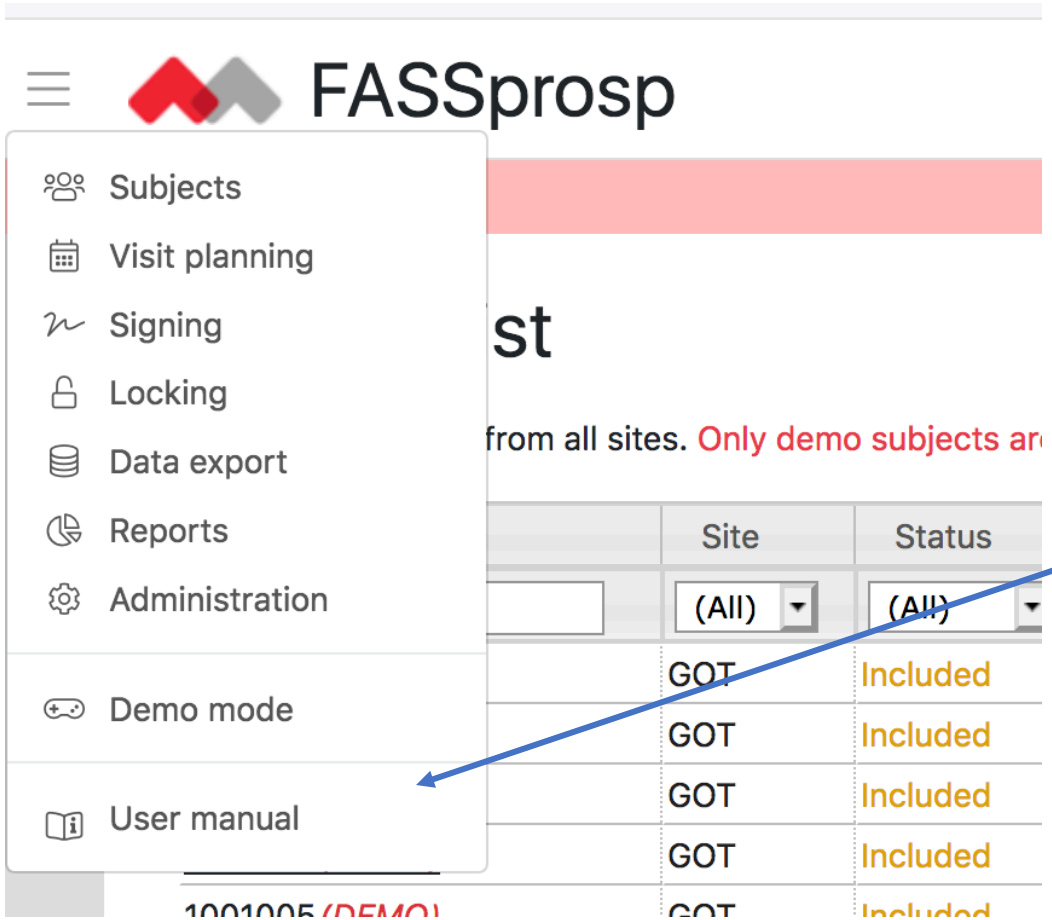
- Upload images and clips to the FTPS server, instructions in the Process document

General principles

FASSprosp

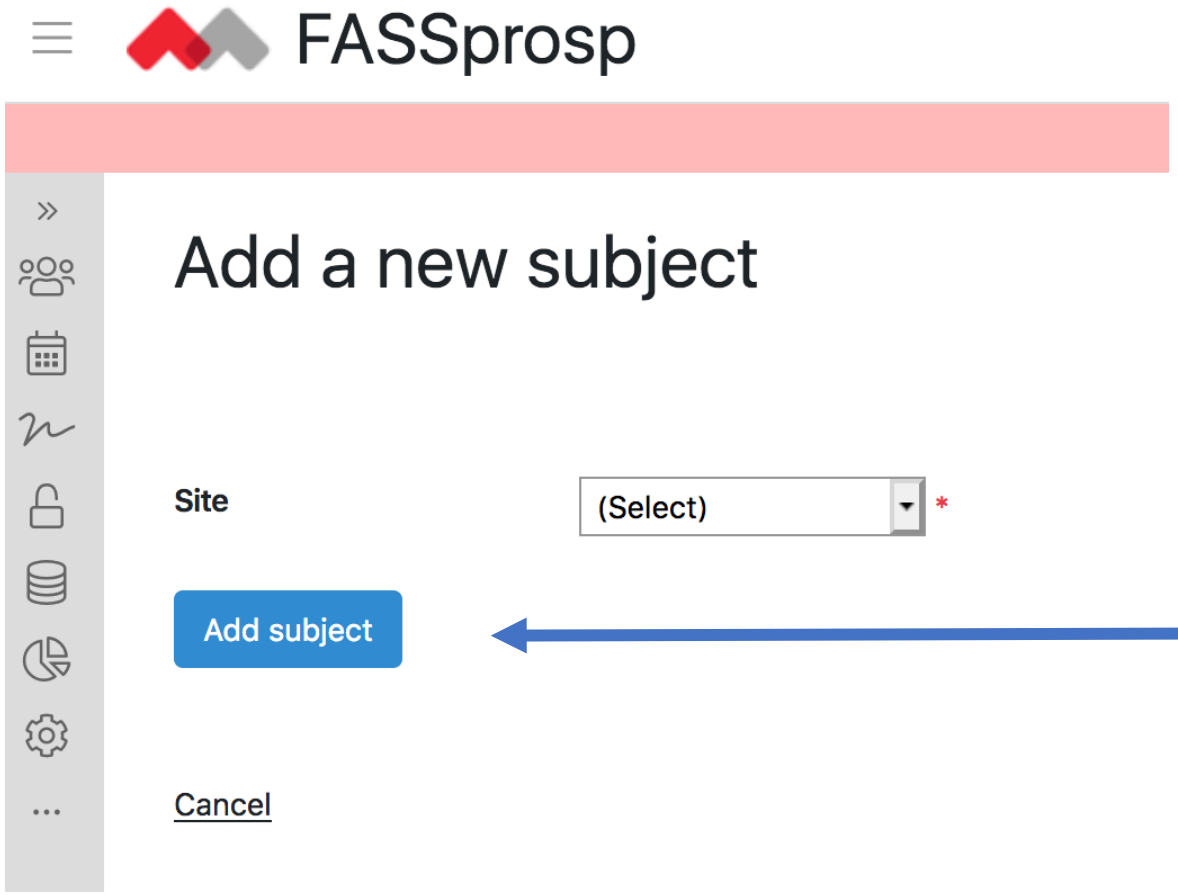
1. Help and instructions for the user; user manual MediCase
2. Add a new subject
3. Warnings, out of expected range
4. When data is not available

1. User manual



User manual

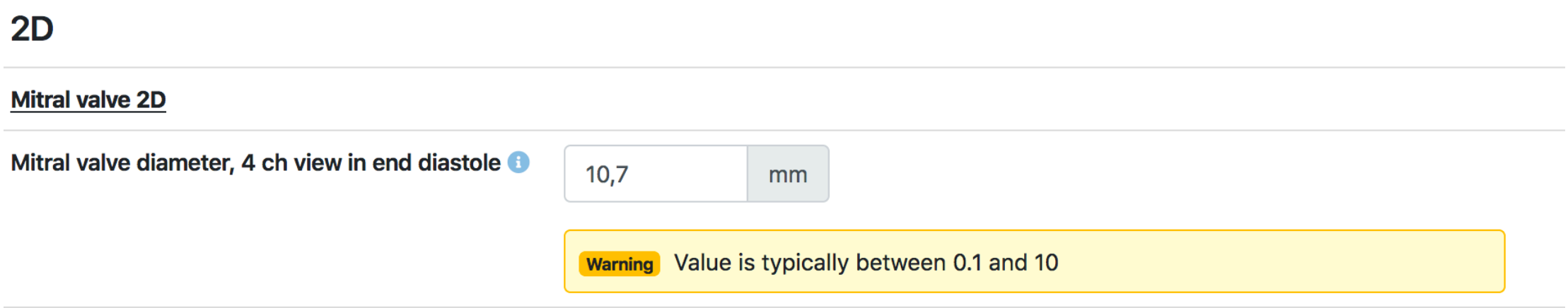
2. Add a new subject



Add a new subject,
below, on the left-hand side of the screen

3. Warnings

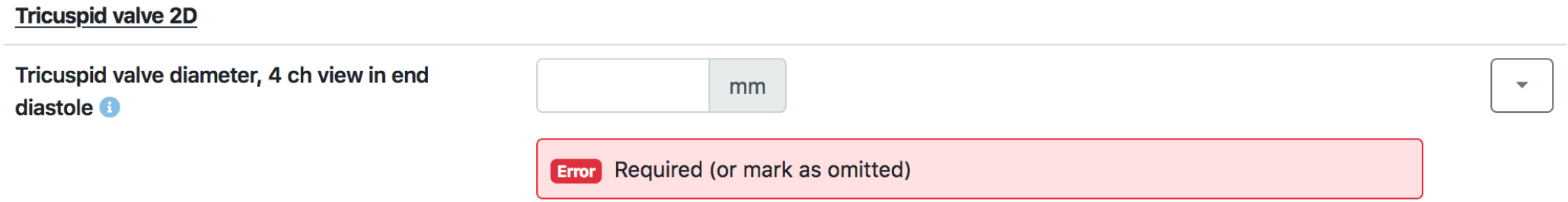
FASSprosp

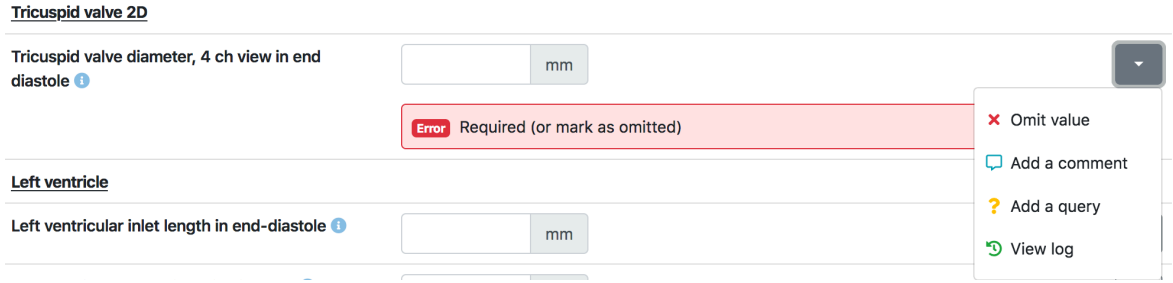


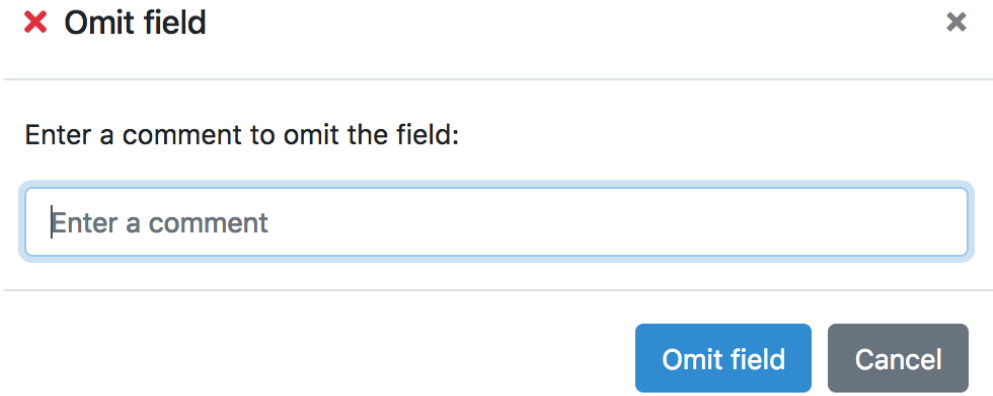
A warning is a note that the value could be out of range, but with no other consequences for data input.

➢ Check the value and continue without changes, if the value is what you want to put into the system

4. Data not available FASSprosp







If data is not available, the field needs to be marked as omitted and note a comment

eCRFs

eCRFs in Medicase

- Inclusion
- Baseline fetal echo at 23+0 to 31+6 GW
- Follow up fetal echo at 33+0 to 34+6 GW
- Neonatal
- Follow-up at 2 years of age
- Additional eCRFs

Inclusion

FASSprosp

- **Select site when adding a new subject**
- Select your workplace/site

- **Eligibility screening and inclusion**
- Check that inclusion and exclusion criteria are satisfied

- **Inclusion**
- Confirm that the case can be included, include subject

Baseline Fetal Echo, 23 + 0 to 31 + 6 GW

- **Baseline Fetal Echo at 23+0 to 31+6 gestational weeks**

Upload to FTPS server

- **Additional Baseline Fetal Echo**
- If an intervention is decided later, after the upload of a Baseline fetal echo, *an additional baseline fetal echo should be added*. This fetal echo should be the last echo before intervention

Upload to FTPS server

Add visit "Additional Baseline Fetal Echo"

FASSprosp

Follow- up fetal echo, 33+0 to 34+6 GW

- **Follow up fetal echo at 33+0 to 34 + 6 GW**

Upload to FTPS server

FASSprosp

Neonatal

- **Birth**
- Clinical data

- **Postnatal echo**
- First full study after birth and before an intervention, surgery or cath (except emergency atrial septostomy).

Upload to FTPS server

- **Neonatal clinical diagnosis**
- The diagnosis given before the first intervention, surgery or cath (except emergency atrial septostomy)

- **Neonatal discharge**
- Type of circulation at discharge

- **Clinical cardiac diagnosis at discharge**

FASSprosp

Follow-up at 2 years of age

FASSprosp

UV and BV	• **2-years follow-up** • Type of circulation- UV or BV • Growth, neurological sequelae
BV	•**Pulmonary hypertension, only if BV circulation**
BV	•**Clinical cardiac diagnosis, only if BV circulation**
UV and BV	•**Summary of clinical condition**

Additional eCRFs

- **Use one eCRF *per* procedure**
  - Counselling on fetal valvuloplasty
  - Fetal intervention
- **Use one single eCRF for *all* procedures**
  - Postnatal procedures
- **At the end of study use the eCRF ”Subject termination”**

➢ End of study; ToP, IUFD, postnatal death, HTX, lost to follow-up, withdrawn consent and completion of study at 2 years of age

More than one site

There is the possibility that more than one site can be involved in a case.

Example:

- Site A- Fetal diagnostic center
- Site B- Fetal cardiac intervention center
- Site C - Postnatal intervention center

➢Site A “Adds a new subject” in the MediCase database

➢Site A gives the right to Site B and C to access Site A (Contact Study coordinator/PI)

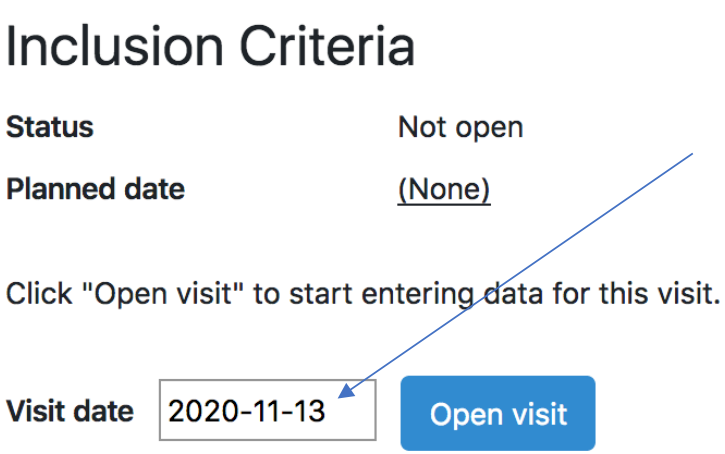
➢Site A gives the case-Id to Site B and C

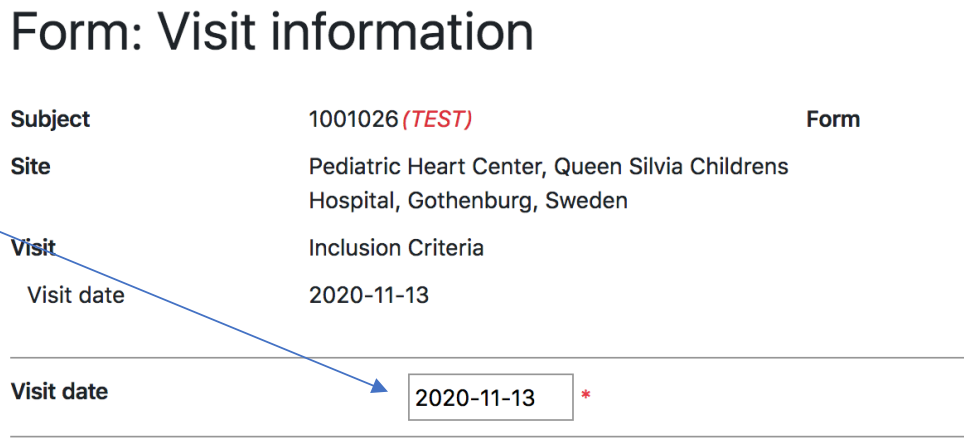
➢ Site B and C add relevant data in the MediCase database

Retrospective data input

- “Date of entry”- the date when data input is made
- “Visit date” - the date when the case was seen

- If visit date ≠ date of entry; change visit date





Thank you for your cooperation and support

FASSprosp