

ERN eUROGEN registry FAQ Common Data Elements

Version 20-10-2022

In case of questions, please contact Lotte Boormans via lotte.boormans@radboudumc.nl.

ERN eUROGEN registry Project Leader	<i>Wout Feitz (wout.feitz@radboudumc.nl)</i>
ERN eUROGEN registry Coordinator	<i>Loes van der Zanden (loes.vanderzanden@radboudumc.nl)</i>
ERN eUROGEN registry Manager	<i>Lotte Boormans (lotte.boormans@radboudumc.nl)</i>
ERN eUROGEN registry Developer	<i>Isabel Hageman (isabel.hageman@radboudumc.nl)</i>
ERN eUROGEN registry Quality Coordinator	<i>Wim Witjes (wim.witjes@radboudumc.nl)</i>
Project Steering Committee (PSC)	<i>Wout Feitz (wout.feitz@radboudumc.nl)</i> <i>Loes van der Zanden (loes.vanderzanden@radboudumc.nl)</i> <i>Darren Shilhan (darren.shilhan@radboudumc.nl)</i> <i>Wim Witjes (wim.witjes@radboudumc.nl)</i>
Advisory Board (AB)	<i>Jorgen Thorup (joergen.mogens.thorup@regionh.dk)</i> <i>Kate Abrahamsson (kate.abrahamsson@vqregion.se)</i> <i>Vijay Sangar (vijay.sangar@nhs.net)</i> <i>Dalia Aminoff (dalia.aminoff@gmail.com)</i> <i>Nicole Schwarzer (info@soma-ev.de)</i>

QUESTIONS

General

Question: Can I complete the Common Data Elements without informed consent?

Answer: No, you may not according to the patient privacy protection rules of the General Data Protection Regulation (GDPR).

Question: Can I start with the Common Data Elements, even though I don't yet have all information to complete the Clinical Practice Snapshot?

Answer: Yes, you can. You can come back to continue registration of the Clinical Practice Snapshot of this patient.

Question: I am still waiting on some information, can I come back to complete the Common Data Elements later?

Answer: Yes, if you are eager to get started without all information, you can. You can then come back to continue registration of this patient.

Care pathway

2.5 ITEM: Start date of treatment

Question: What is meant with the start date of treatment?

Answer: The date the patient started the treatment for their disease that made them eligible for ERN eUROGEN. first came to the hospital for this specific diagnosis or for symptoms that lead to the diagnosis.

- For Workstream 1 (congenital anomalies) and Workstream 3 (tumours), the start date of treatment is the date the patients first came to the hospital for the specific diagnosis or for symptoms that lead to the diagnosis.
 - For congenital defects (WS1) discovered at birth in your hospital, the date of first contact may be equal to the date of birth.
 - For patients diagnosed at and referred from another centre, the date of first visit/consultation at your hospital is the first date of contact. This may result in the date of first contact being after the date of onset of symptoms or date of diagnosis.
- For Workstream 2 (functional condition requiring highly specialized surgery), the start date of treatment is their surgery date. Patients can have e.g. stress incontinence complaints for years, while stress incontinence is not a rare condition on its own and only falls under the ERN eUROGEN scope once they have a AMS800/ProAct/Redo SUI/other complicated surgery to treat the stress incontinence. This allows us to correctly collect data of their first treatment year after the complicated/complex surgery.

Question: What is meant with "specialised centre"?

Answer: The hospital / Health Care Provider that you are currently working for and completing registration for. Meaning, you register the date of the first time the patient visited your Health Care Provider for this diagnosis.

- What if a patient has been referred from another centre to your hospital?
 - Select the date the patient first visited your hospital, even though this may result in the date of first contact being *after* the date of onset of symptoms or date of diagnosis.

Disease history

2.6 ITEM: Moment of onset

Question: What date should I select if there were no clear symptoms?

Answer: The date where a diagnosis/issue was first suspected as noted in the medical file.

- What if it was an accidental finding?
 - Select the date of diagnostic test (e.g. date of CT scan which showed a tumour).
- What if symptoms were caused by an intervention (iatrogenic)?

- Select the date of the causing intervention.

2.7.1 ITEM: **Moment of diagnosis**

Question: What date should I select when a diagnosis has been suspected for a while, but only later confirmed?

Answer: Select the date of when the diagnosis was confirmed (e.g., date of diagnostic test which confirmed the diagnosis).

