



Common Data Elements

VERSION 220310

1. Informed consent:
 - a. Patient included for retrospective or prospective study? [Radio button, one selection]
 retrospective prospective
 - b. Patient/parent(s)/legal representative(s) has/have given informed consent for the data being included in the ERN eUROGEN registry [Radio button, one selection]
 yes no
(If no, answer question 1c and continue with 1e. If yes, answer question 1e and further)
 - c. Why is there no informed consent signed? [Radio button, one selection]
 opt-out procedure other
(If other, answer question 1d)
 - d. Specification other reason [String]
 - e. Who signed the informed consent form? [Tick-box, multiple selection]
 Patient that reached the age of legal majority Date [Date, dd/mm/yy format; at/after DoB]
 Parent(s) / legal representative(s) Date [Date, dd/mm/yy format; at/after DoB]
 - f. Consent to the reuse of pseudonymized data to support commercial projects aimed to improve healthcare [Radio button, one selection]
 yes no unknown
 - g. Consent to the transfer of pseudonymized data to non-EU countries, in compliance with GDPR, to support projects aimed to improve healthcare [Radio button, one selection]
 yes no unknown
 - h. Consent to the linking of pseudonymized data to existing databases/registries to improve healthcare [Radio button, one selection]
 yes no unknown
 - i. Agree to be contacted by medical doctor about research projects and/or clinical studies related to condition [Radio button, one selection]
 yes no unknown
 - j. Consent to receive in the future, if applicable, a link to an online questionnaire on the email address written on the consent form [String]
 yes no unknown
2. Personal information:
 - a. SPIDER Pseudonym: [String]
 - b. Date of birth: [Date, dd/mm/yy format]
 - c. Birth sex: [Radio button, one selection]
 Female Male
 Undetermined Foetus (unknown)
3. Patient Status:
 - a. Patient's status: [Radio button, one selection]
 Alive Dead
 Lost in follow-up Opted-out
(If dead, answer question 3b)
 - b. Date of death: [Date, dd/mm/yy format; at/after DoB]
4. Care pathway:
 - a. Date of first contact with specialised centre: [Date, dd/mm/yy format; at/after DoB]

5. Disease history:

a. Moment of onset (at which symptoms/signs first appeared): [Radio button, one selection]

- Antenatal At birth
 After birth Undetermined

(If after birth, answer question 5b)

b. Date of onset: [Date, dd/mm/yy format; at/after DoB]

c. Is there a diagnosis? [Radio button, one selection]

- yes no

(If yes, answer question 5d, f, g and h. If no, answer question 6a)

d. Moment of diagnosis: [Radio button, one selection]

- Antenatal At birth
 After birth Undetermined

(If after birth, answer question 5e)

e. Date of diagnosis: [Date, dd/mm/yy format; at/after DoB]

Rare disease's diagnosis: [Drop-down menus with one selection each]

- f. Workstream
g. Sub-thematic area of expertise
h. Rare or complex disease

6. Other information about diagnosis:

a. Phenotype of undiagnosed case: [String]

phenotype (HPO)

b. Is there a genetic diagnosis for this patient? [Radio button, one selection]

- yes no

(If yes, answer question 6c)

c. Genetic diagnosis retained by the specialized centre: [String]

*international classification of mutations (HGVS, strongly recommended - see link**) /HGNC/OMIM code*

7. Biological sample available: [Radio button, one selection]

- yes no unknown

*: <http://www.orphadata.org/cgi-bin/inc/product1.inc.php>

** : <http://www.hgvs.org>

***: <http://www.who.int/classifications/icf/whodasii/en/>



European
Reference
Networks

https://ec.europa.eu/health/ern_en



European
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Network

for rare or low prevalence
complex diseases

Network
Urogenital Diseases
(ERN eUROGEN)

<http://eurogen-ern.eu/>



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