



EuRREB Project Manager Tess de Rooij

Leiden University Medical Center

‘Ethics approval and data sharing process’



EuRREB

European Registries for Rare
Endocrine and Bone conditions

Ethics approval and data sharing process

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Ethics Approval



Challenges

Procedures

- Unclear procedures in centres
 - Not all require local approval
 - Clinicians/researchers rarely know the procedure of their HCP/country
- Standardisation not possible

Resources

- Complicated and long procedures require a time investment, which creates a barrier
- Initial enthusiasm for obtaining ethics approval often fades due to this barrier
 - 53% of the HCPs contacting us for assistance, never followed up on it
- The Registries now spend 0.4 FTE on guiding and supporting all ethics approvals

Restrictions

- DPIA (Data Protection Impact Assessment) cannot be shared fully with external parties, but some ethic committees require this
- Next to local requirements, there are national and GDPR requirements

Best practices & possible solutions

Procedures

- JDRA (Joint Data Registries Agreement) instead of 2 DSA's
 - JDRA covers:
HCP -> registries AND
registries -> researchers
- PIF and ICF templates in 12 European languages, only local adjustments needed
- JDRA/DSA templates* for UK, Italy and the Netherlands
 - * Template = approved & signed by 1+ centre with minimal adjustments & max. 2 feedback rounds

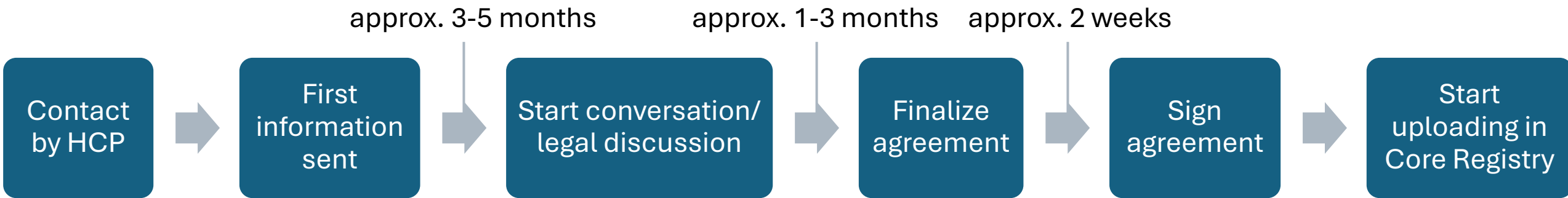
Resources

- Trying to simplify procedures by providing templates

Restrictions

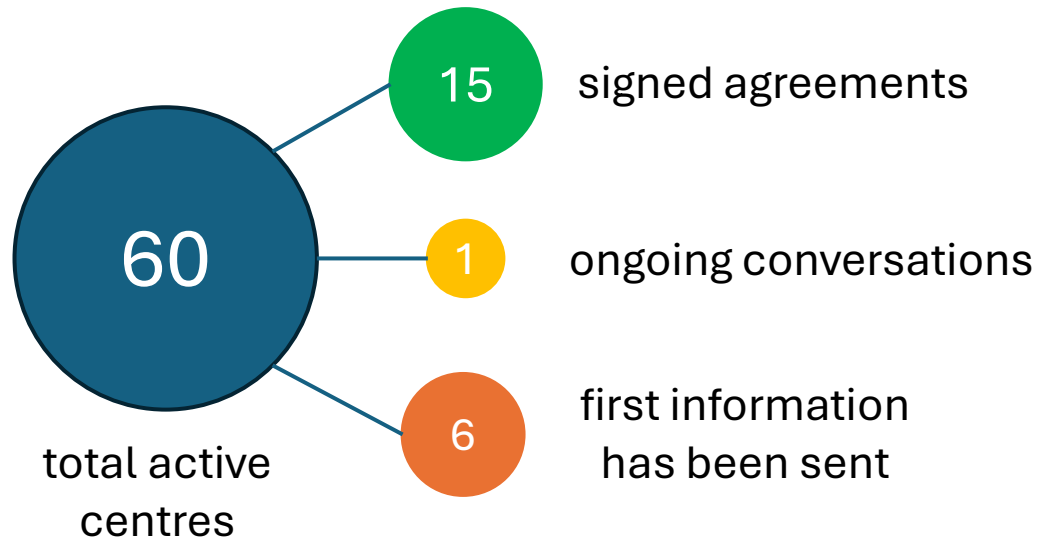
- DPIA adjusted for external use, have meetings with legal departments if needed
- Trying to identify the different requirements for different countries

Current process



Status of Core Registry centres

Active centres in Core Registry



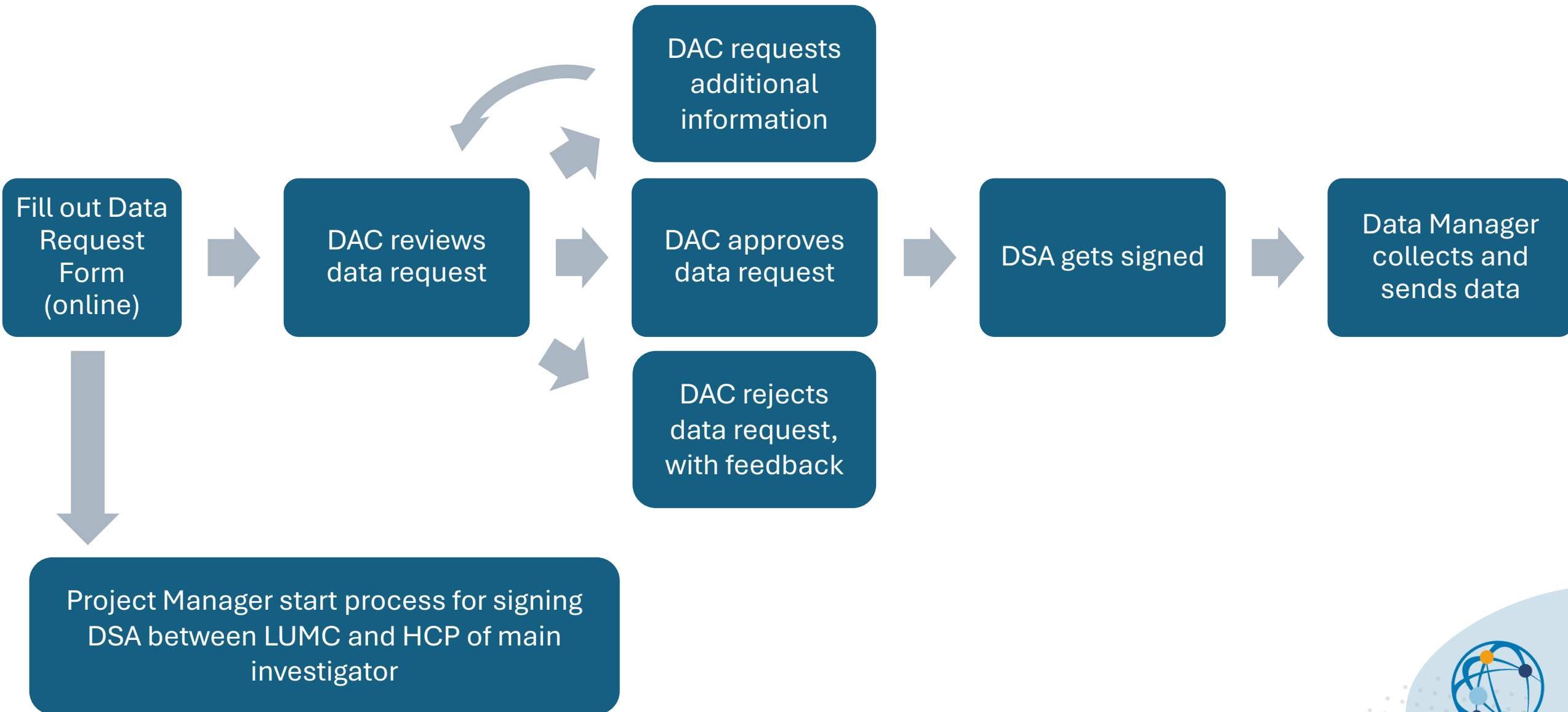
Centres not active in Core Registry (yet)



Data Sharing



Current process



Past data requests

Date	Data from	Name of data request	Status
19-Oct-22	e-REC	Health care for transgender adolescents	Approved
14-Dec-22	Core Registry	Parathyroid carcinoma module	Approved
20-Dec-22	e-REC	CaMelia	Approved
30-Dec-22	e-REC	Mosaicisms in XLH	Approved
3-Jan-23	e-REC	Cushing VTE survey	Approved
9-Mar-23	e-REC	iPSD/PHP	Approved
26-Aug-23	Core Registry	Rare Obesity	Approved
14-Feb-24	e-REC Core Registry	Achondroplasia registry	Approved
5-Mar-24	Core Registry	Healthcare mapping transgender adolescents	Approved
24-Apr-24	e-REC Core Registry	Melorheostosis	Approved
22-Nov-24	Core Registry	PANOMEN Study	Approved
22-Nov-24	Core Registry	Transcription factors	Approved
8-Mar-25	e-REC Core Registry	Transition research using registries	Approved
19-Mar-25	Core Registry	ped-DTC STRATIFY	Approved



Current data requests in review

Date	Data from	Name of data request
9-Aug-25	Core Registry	Transition research using registries
11-Aug-25	Core Registry	Cross-ERN Use Case
3-Sep-25	Core Registry	MEN1 Registry



Thank you

Ways to contact us:



eurreb.eu



registries@lumc.nl



drop-in sessions via Zoom



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