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Collaborate - Track 1

Landscape

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DISCLAIMER:

The views presented here do not reflect the official position of the European Commission.

CTR COLLABORATE project - deliverables

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1. **Mapping of landscape of part I assessment NCA/Ethics (survey)**
2. Issues requiring optimisation of work procedures:
    - Issue list (requirements and templates, Part I and II alignment, RFI optimisation, strengthening the role of the RMS, risk adaption)
    - Proposal for solutions issue list
3. Joined (NCA and Ethics) update of best practices
4. Implementation of best practices via CTCG roundtables/workshops to support harmonisation and collaboration.
5. Communication NCA/Ethics/Sponsor

The Survey

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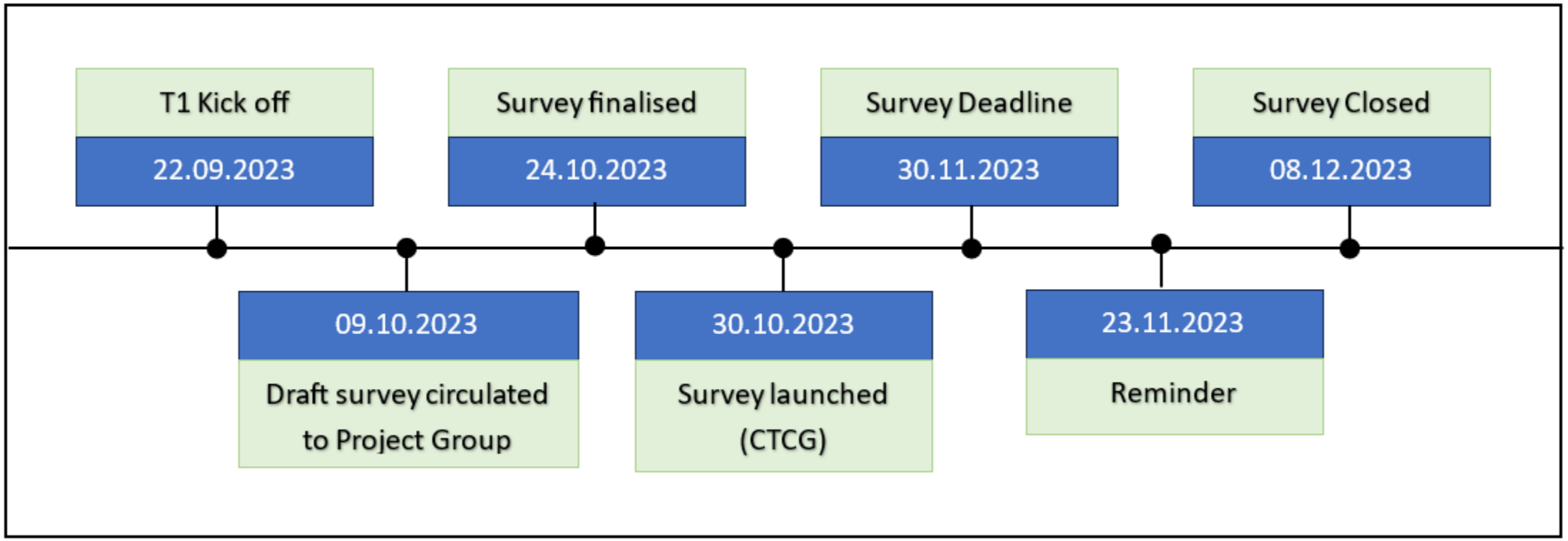
- Created with **EU-Survey (COM Tool)**
- About **90 questions** (single choice, multiple choice and free text) in **11 sections on procedural aspects**



Responders & NCA/EC

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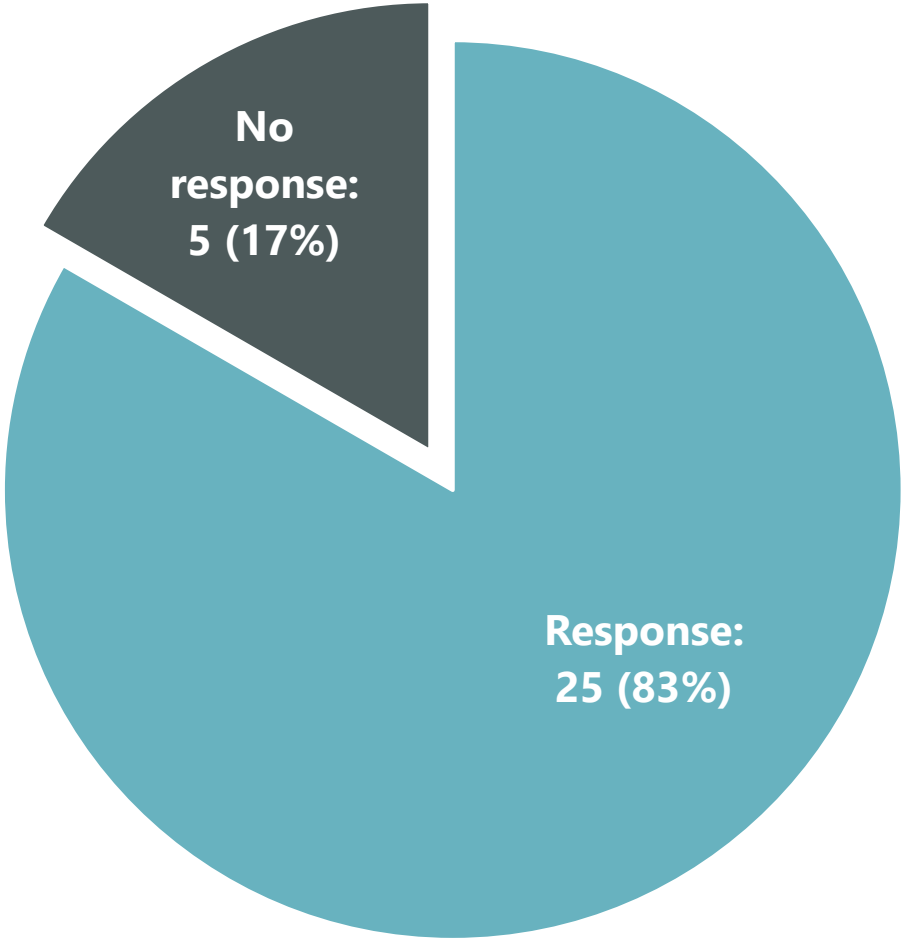

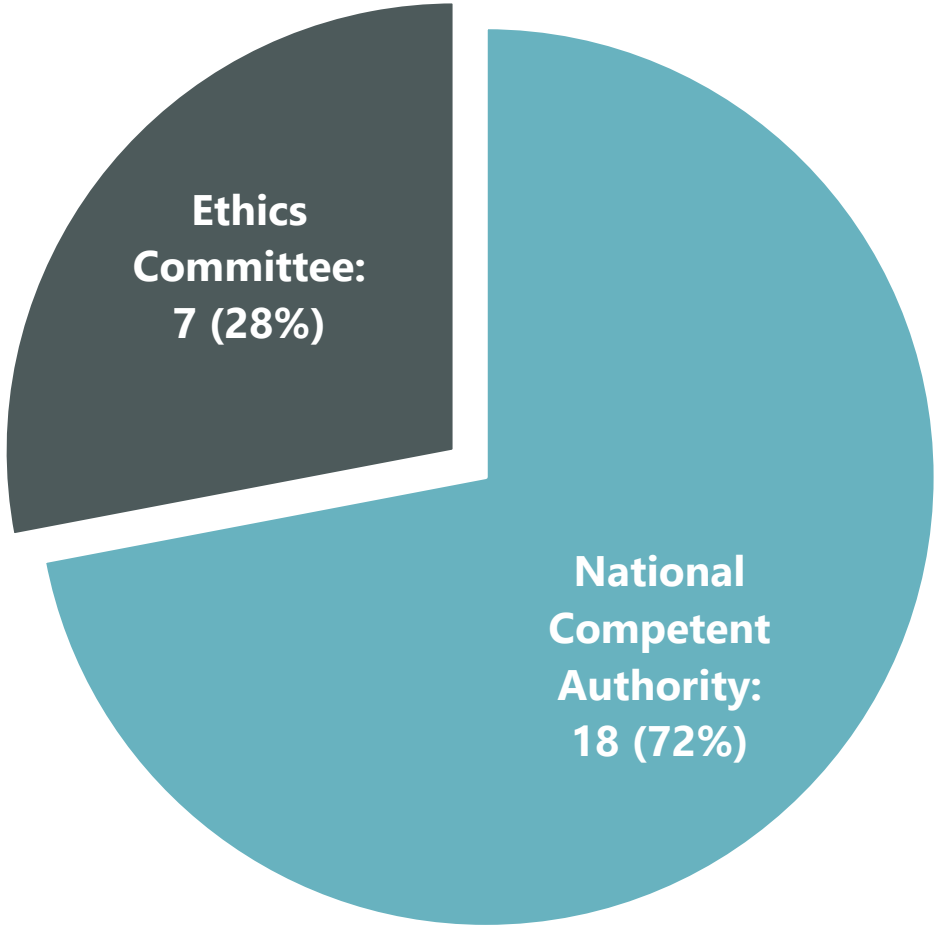

Number of Ethics Committees (EC)

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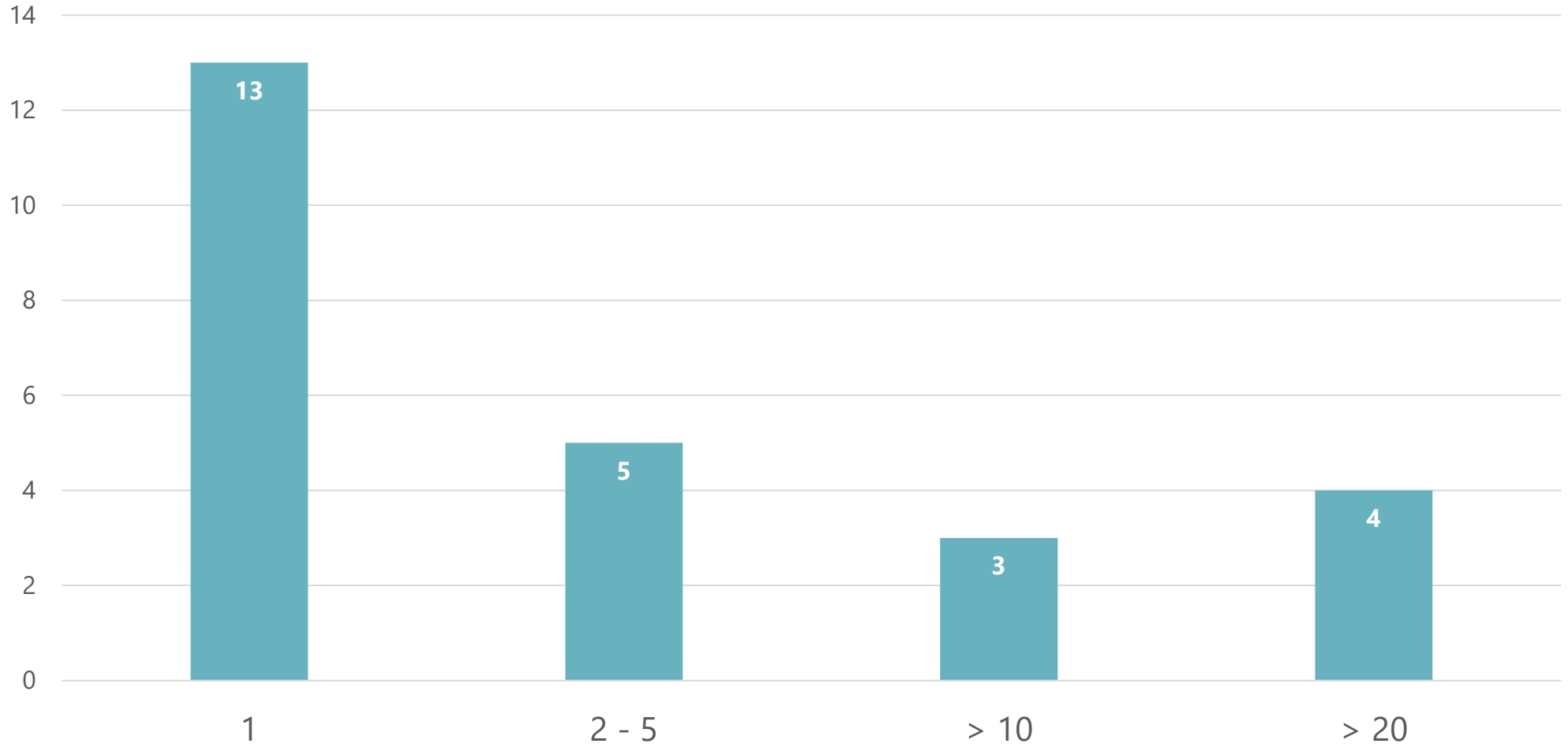

EC structure

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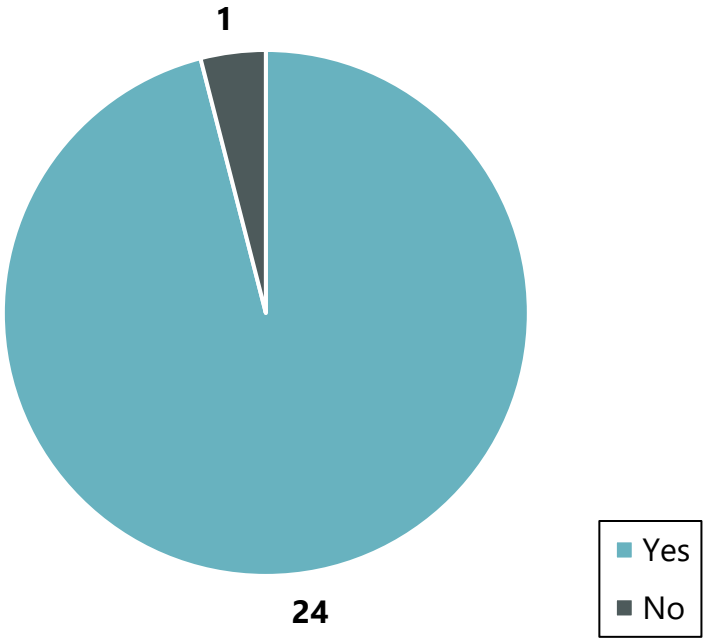
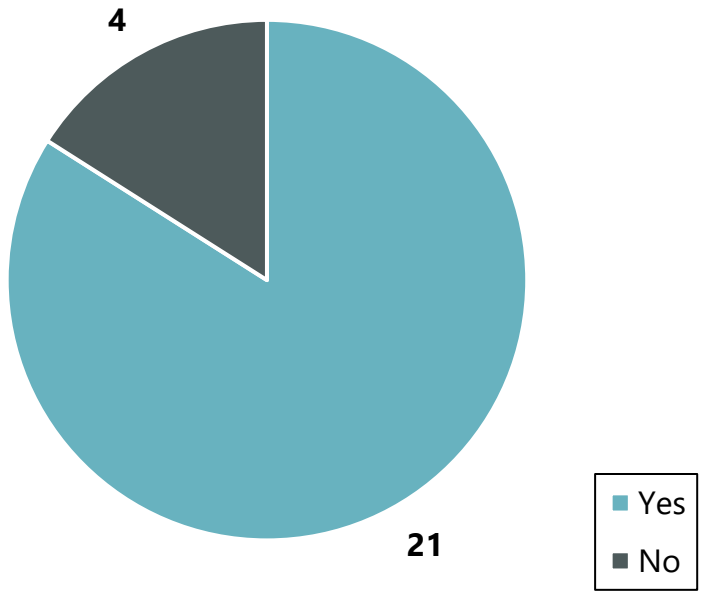
National Law?

Is the involvement of Ethics Committees under the CTR in your Member State regulated in the National Law?



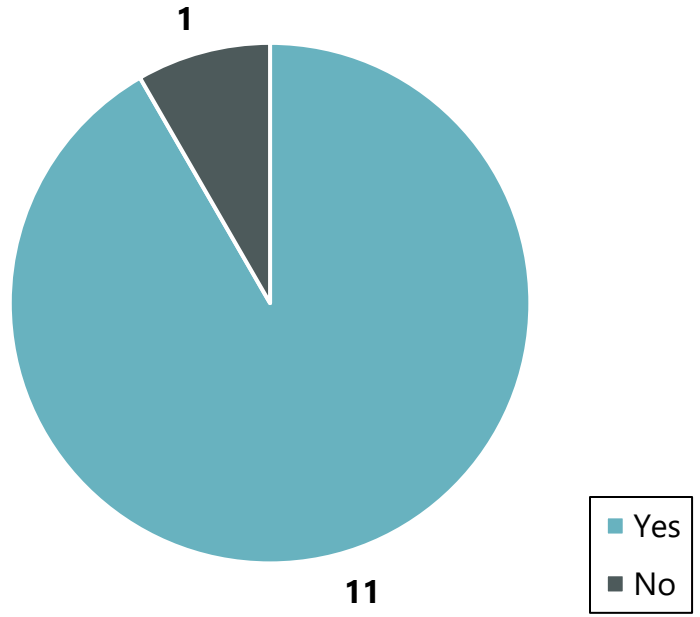
SOP?

Are Standard Operating Procedures (SOPs) or Best Practices in place in your Member State for Ethics Committees working under the CTR?



Central coordination? n = 12

Is there a centralised structure of Ethics Committees in your Member State with the role of study assignment, coordination, or oversight?



13 MSC have only 1 EC.

CTIS use and IT structure

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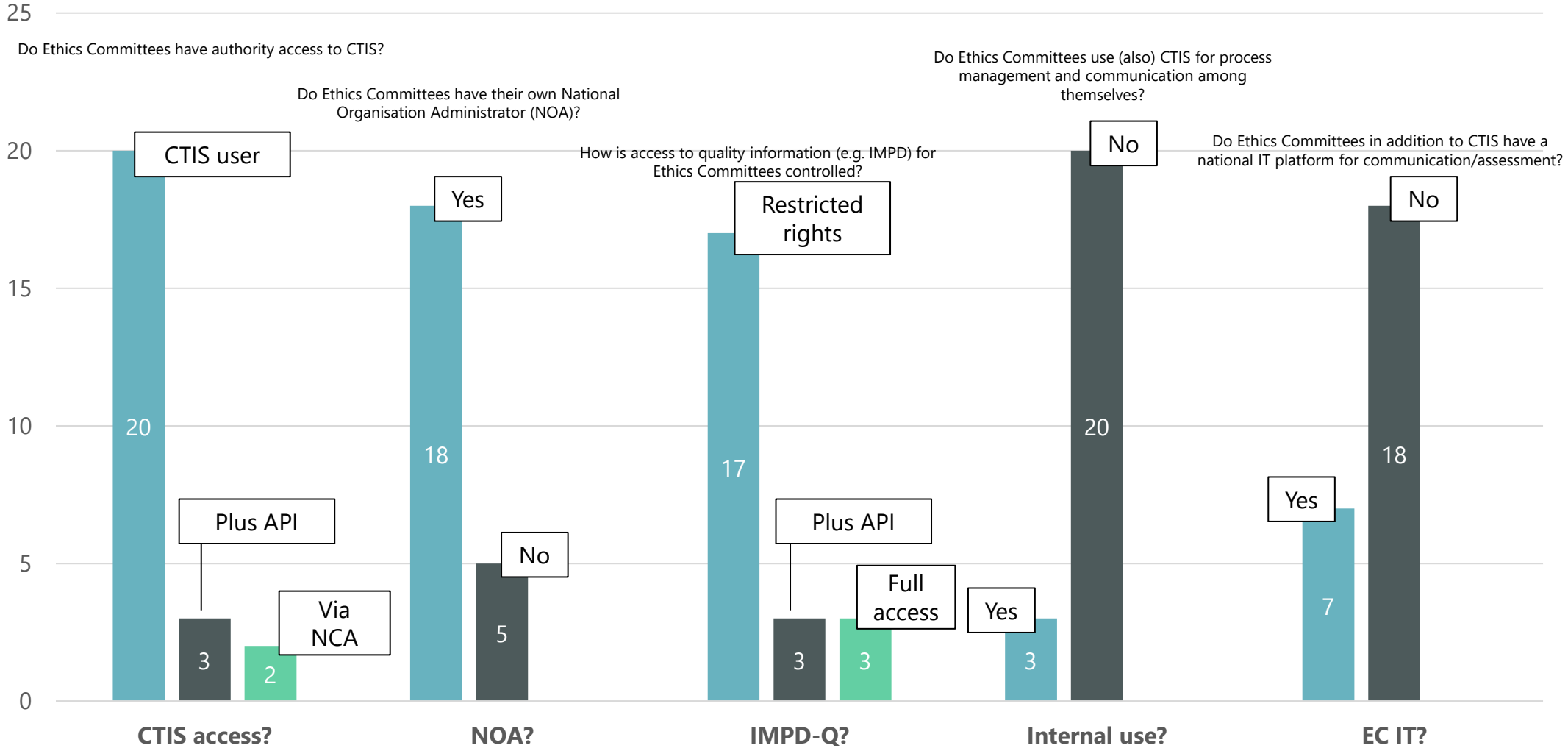

RMS & Validation

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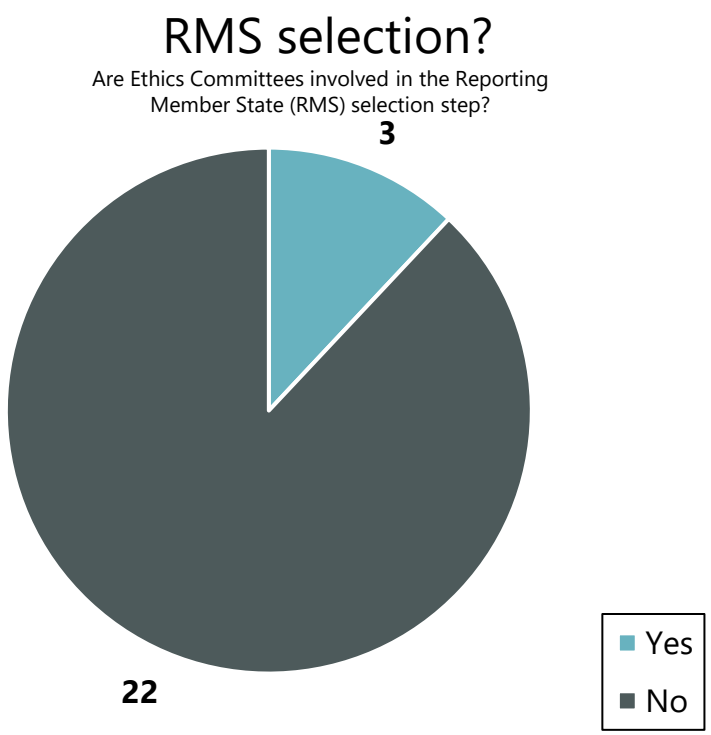

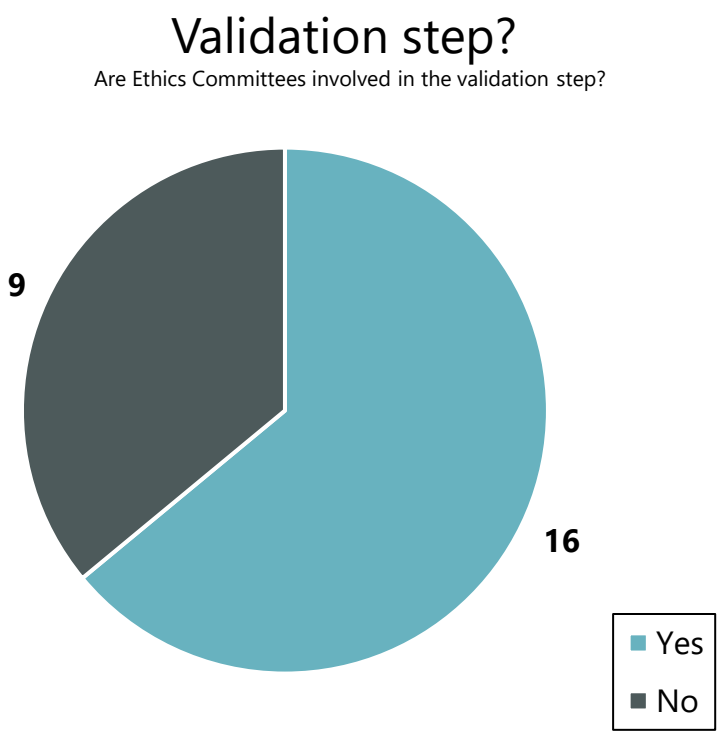

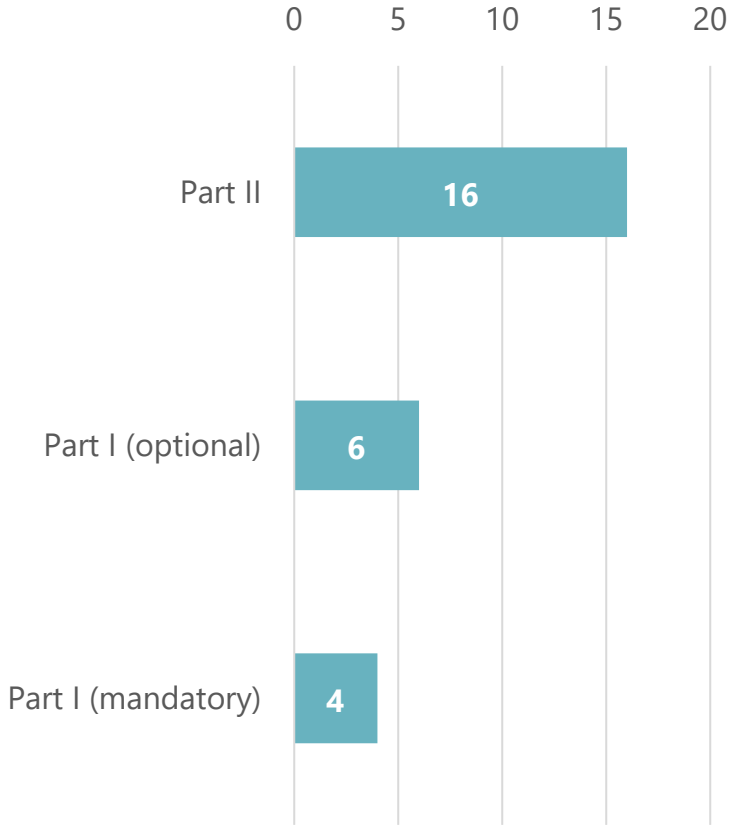

n=16

Validation process (n = 16)

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	Subtask	Task assigned	Outside of CTIS	Not involved
Document validation considerations	**13**	**2**	**1**	**-**
Consoldiate considerations	**4**	**1**	**-**	**11**
Submit RFI (if RMS)	**2**	**1**	**-**	**13**
Assess RFI	**14**	**1**	**1**	**-**
Submit validation decision (if RMS)	**1**	**1**	**-**	**14**

Part I assessment

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- Only two MS are not involving EC in Part I, the others do (n =23).
- 10 MS do not involve ECs in the population of the DAR (n = 13).

Assessment steps Part I (n = 23)

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	Subtask	Task assigned	Outside of CTIS	Not involved
Circulate draft assessment report (if RMS)	7	1	5	10
Document considerations Part I	16	1	6	-
Consoldiate considerations	4	1	2	10
Submit RFI (if RMS)	-	1	3	19
Assess RFI	16	1	5	1
Submit Part I conclusion (if RMS)	-	1	5	17

Assessment report types Part I (n= 13)

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	Complete	Contribute	Not involved
Administrative report	2	1	10
Quality report	1	-	12
Preclinical report	2	3	8
Clinical report	2	11	-
Statistical report	4	6	3
Regulatory report	2	3	8
Conclusion report	2	5	6

Part II assessment

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- All MSC involve Ethics Committees in Part II (n = 25)
- The full scope of Article 7 is always applied.

Assessment steps Part II (n = 25)

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	Subtask	Task assigned	Outside of CTIS	Not involved
Document considerations Part II	**3**	**20**	**2**	**-**
Consoldiate considerations	**3**	**20**	**-**	**2**
Submit RFI	**2**	**21**	**-**	**2**
Assess RFI	**3**	**20**	**2**	**-**
Submit Part II conclusion	**2**	**21**	**-**	**2**

Part II assessment report types (Part II)

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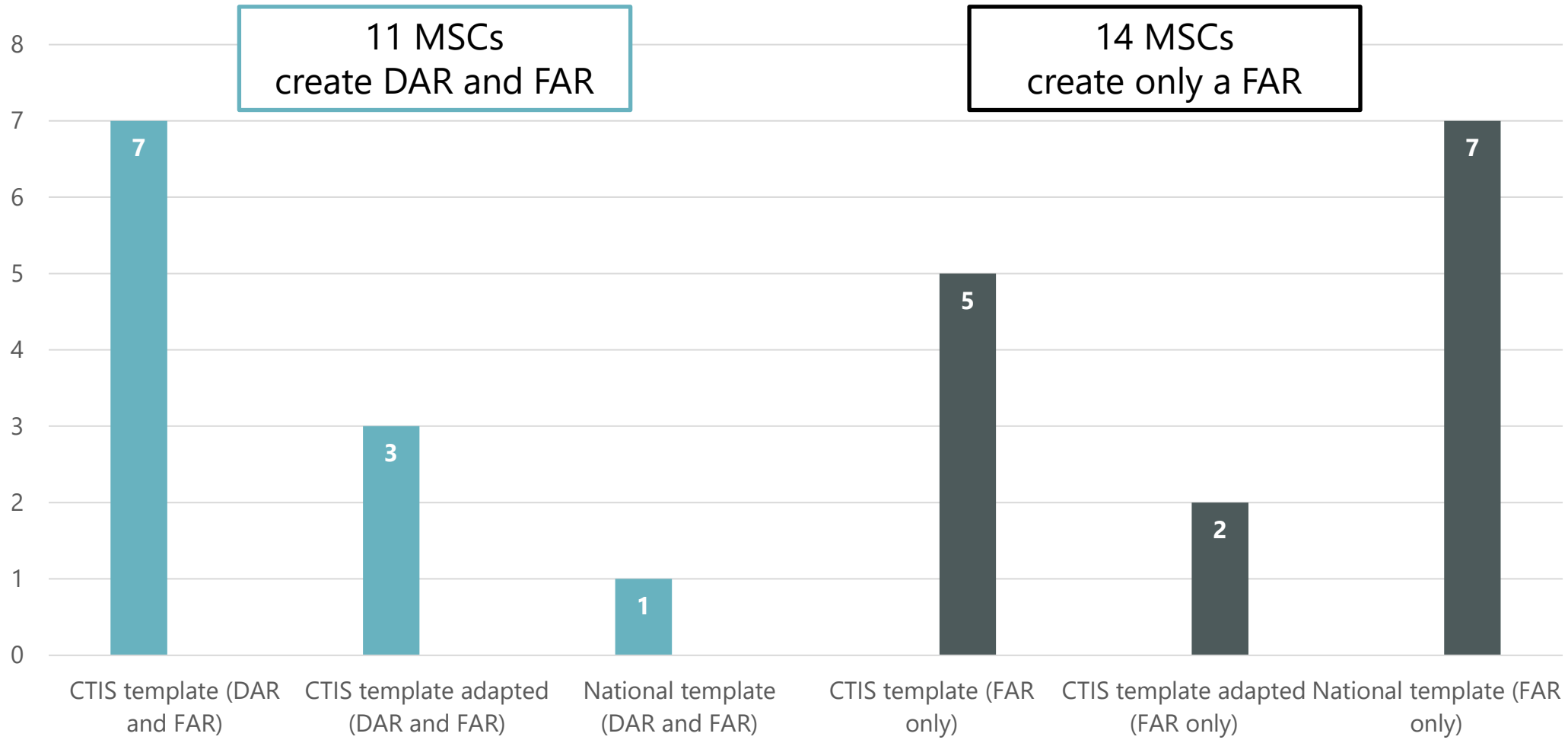

Strategies for the assessment process

Three different approaches.

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1. **The complete process or a sub-process (Part II assessment) is delegated** to the EC via „Assign Task“.

2. **ECs contribute to the „assessment steps“ (reports, considerations, consolidation and RFI assessment) via a subtask**;
   not involved in „executive“ steps (submit RFI and submit conclusion)

3. **ECs contribute to the „assessment steps“ (reports, considerations, consolidation and RFI assessment) outside of CTIS**;
   not involved in „executive“ steps (submit RFI and submit conclusion)

National decision

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- In 24 Member States the Single Decision („Authorize“-Task) is taken by the NCA.
- In the Netherlands the CCMO or MREC take the decision.
- There is no difference in responsibilities between mononational and multinational trials.

EC involvement in life-cycle procedures

As a standard process, not a case-by-case basis

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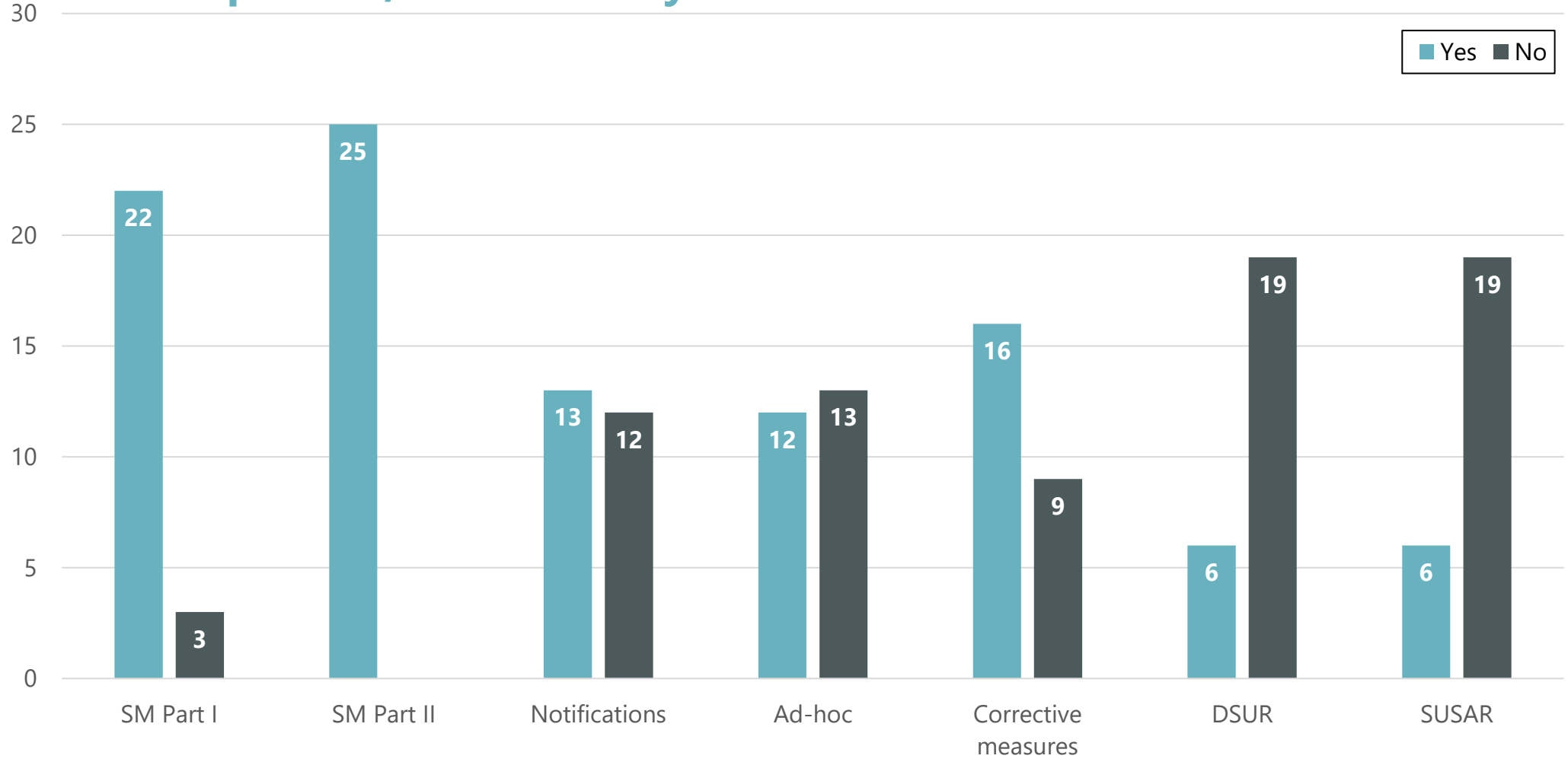

Involvement of EC in all procedures in 6 MSCs.

Involvement of EC in oversight, ad-hoc and corrective measures in additional 5 MSCs.

Interfaces

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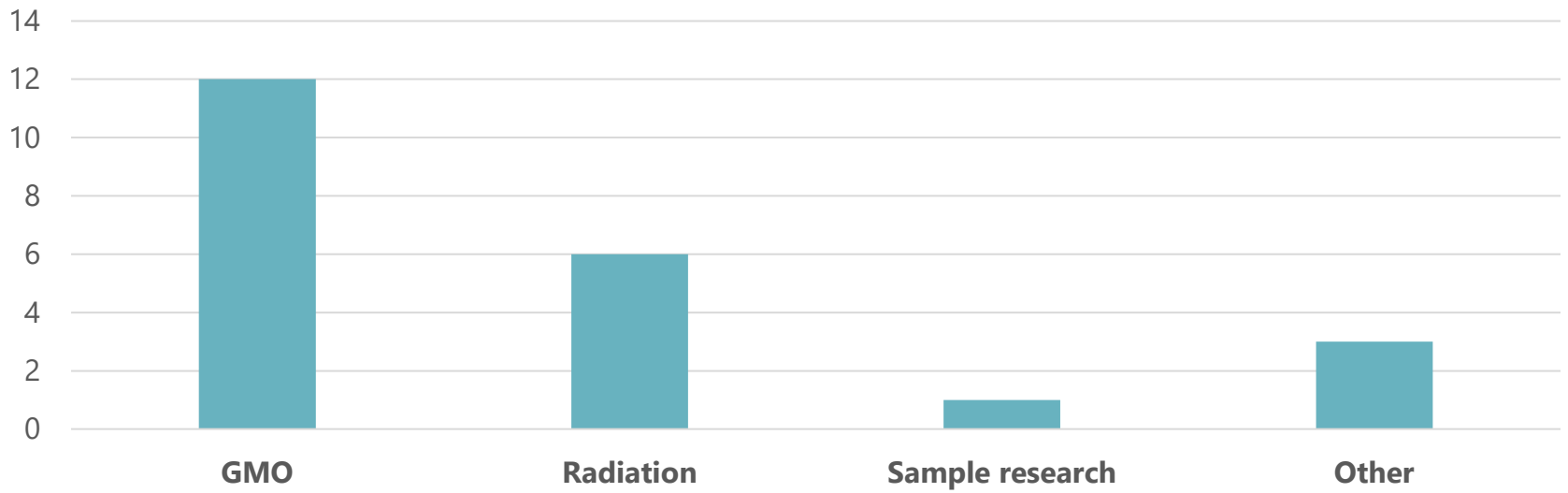
- In 21 MSC CTR Ethics Committees also deal with device/IVD trials.
- In 13 MSC additional approval by other regulatory bodies is required.



Thank you for your attention.

Questions?