

GUIDELINES FOR HRPO TO IMPLEMENT A FAIR DATA POLICY

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OBJECTIVES

- Global feedback
- Create a new RDA WG
- Outline the case statement



METHODOLOGY

- Landscape analysis
- Group activity
- Integration within HDIG activities



LANDSCAPE ANALYSIS

Serena Battaglia

What is happening in your research context?

Responsible people of the Health-Research Performing Organizations do not know how to make FAIR data policies.

Sharing Clinical Trial Data: Challenges and a Way Forward - A Workshop
[<http://nationalacademies.org/hmd/Activities/Research/DrugForum/2019-Nov-18.aspx>]

Researchers are overwhelmed by privacy, legal and ethical issues and they often see RDM/FAIR as a burden. Privacy lawyers are generally saying data cannot be shared either. So researchers aren't seeing the benefit of FAIR yet at our institution.

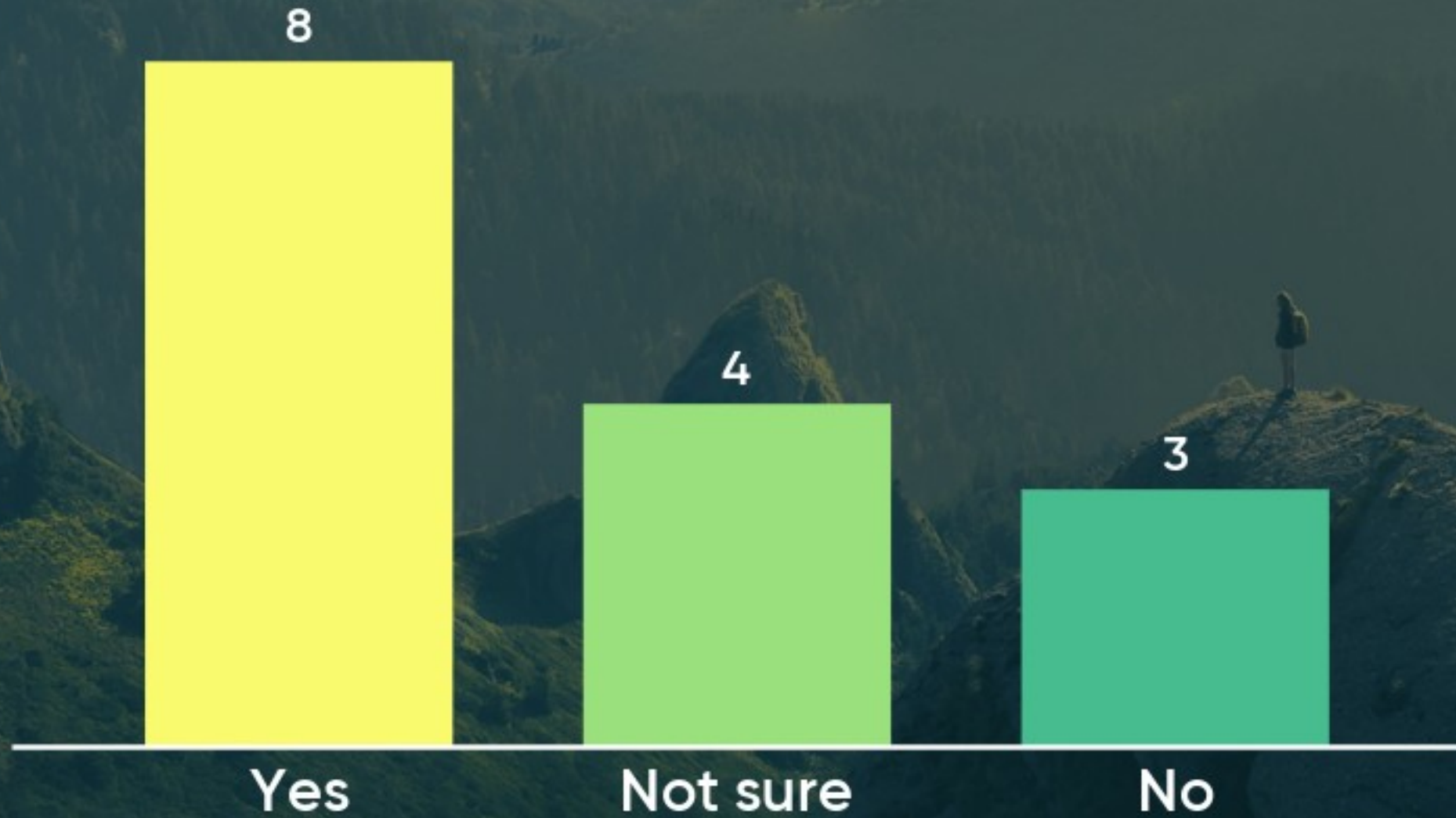
There are many ethical barriers and regulations in a clinical/health environment to data sharing, so I agree that it is essential to define guidelines

GROUP ACTIVITY

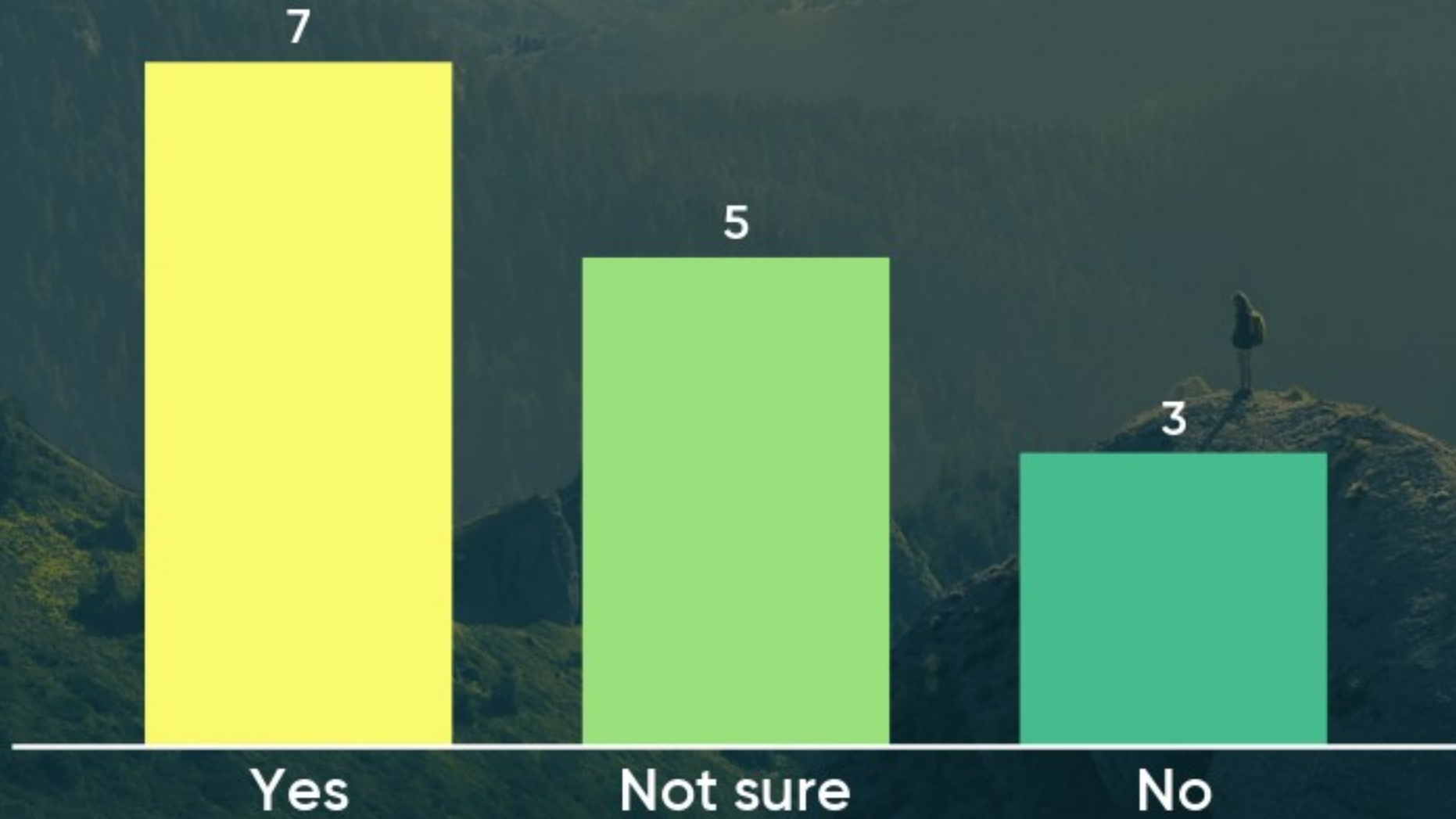
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The researcher is responsible of making research data FAIR



The HRPO is responsible of making research data FAIR



What should include a FAIR data policy in an HRPO?

An audit plan

For HRPO and other stakeholders:
[https://docs.google.com/spreadsheets/d/1-uSocVpju4_fBcMDBgW2LxG3EpvBNRedOQuings2Cok]

Considerations for how to balance making data available, but protection participants

Consent for sharing

Metadata, ontology, licensing options if possible.
Researchers can then choose from those.

Explanation of FAIR data, and benefits of FAIR data. Considerations specific to Health data (sensitivity / privacy) - ethics, consent Guidelines for compliance... and where to get help (or links to this info)

including Data Scientists/Open Scientists in the development of the study design or study planning.

1) Open, Transparent, Version-controlled, and machine-readable data management plans 2) Definition of what workflows are conducted within HRPOs and what information and materials make those workflows machine-readable and reproducible.

A vision (strategic) and an Action plan

What should include a FAIR data policy in an HRPO?

Use of common data elements

Identification of appropriate repositories to submit the data

MONEY!!!! There are not policies without a budget!

Minimum set of requirements for reproducibility.

Data curation workflows & study metadata: extraction processes (eg, source system type, coding scripts with appropriate censure to protect confidentiality/proprietary concerns); data transformation/integration scripts); sharing limitations/reqs.

1) Require DMPs as early as possible in the research process; 2) generally require consent for sharing (with guidance on how to do this); 3) establish and maintain infrastructure

Establish and require courses for early career researchers in open science practices

Establish integrated tools/systems for data management, ethics and privacy assessments to minimize administrative burden on researchers

1) reward mechanisms. 2) PIDs policy. 3) Metadata policy. 4) Identify and deposit in trustworthy repositories.

What should include a FAIR data policy in an HRPO?

Establish integrated tools/systems for data management, ethics and privacy assessments to minimize administrative burden on researchers

Write statement about the policy in Open/FAIR RDM. mechanisms for FAIR data assessment

Raise awareness among researchers, provide training

EARLY DRAFT GUIDELINES

Literature review, focus groups and open surveys to analyze barriers and needs in EU from: Technology, Cultural, Ethics, and Legal point of views.
We've come up with 5 guiding principles and 10 steps



5 principles (draft)



INTEGRATION WITHIN HDIG ACTIVITIES

Leslie McIntosh



WRAP-UP



Ideas for the case statement?

Must reach beyond euro-centric.

List of RDA Groups to interact with (FAIR groups, health groups, skills groups)

HRPOs are in need of clear structured guidance on the FAIR principles and how they could be implemented. Doing this on an international level will promote the open science practices and level playing field that we are hoping to achieve in research

Potentially propose a coordination group wherein this task force team could recruit, synthesize, and leverage ongoing activities and strategically lead implementation and adoption.

Accreditation with FAIR e Seal for HRPO by National Agencies,

Describe potential mechanisms or models for making data available, based on consent.