Good practices and resources to improve the utility of research data in regulatory assessments

EC-Joint Research Centre, Karolinska Institutet, Stockholm University

Webinar, 31 January 2024

European Commission

Agenda

15:00-15:45 Presentations

The challenge of using (non-standard) research data in regulatory assessments and the OECD initiative (Antonio Franco, JRC, OECD WPHA Expert Group on research data)

Experience and contributions from the SciRAP initiative (Anna Beronius, Karolinska Institutet, OECD WPHA Expert Group on research data)

Enabling innovation: from data science research to regulatory application (Philippe Rocca-Serra, University of Oxford, Molecular data production and management of PrecisionTox)

PARC perspective (Iseult Lynch, University of Birmingham, co-lead of PARC WP7 on FAIR data)

15:45-16:30 Q&A and discussion

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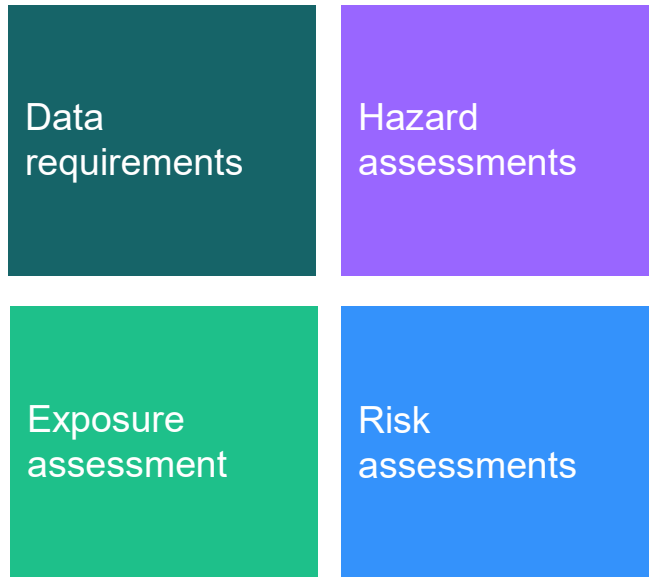
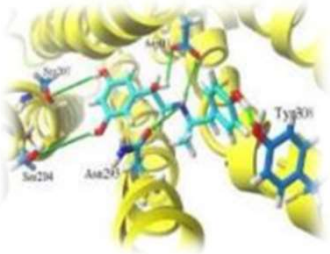
~~Academic~~ Research data

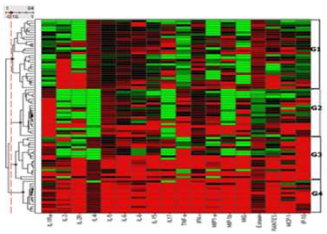
- hazard, exposure and risk assessment data
- generated by scientists from academia, public and private research institutes, industry or NGOs
- published in peer-reviewed scientific literature, curated databases and grey literature

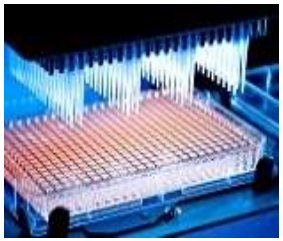
Typically:

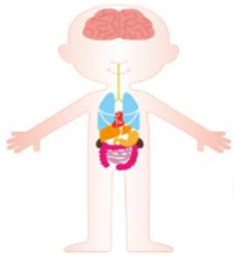
- data not carried out specifically to inform assessments
- non-standard (non-guideline) experimental (animal and non-animal) or computational methods











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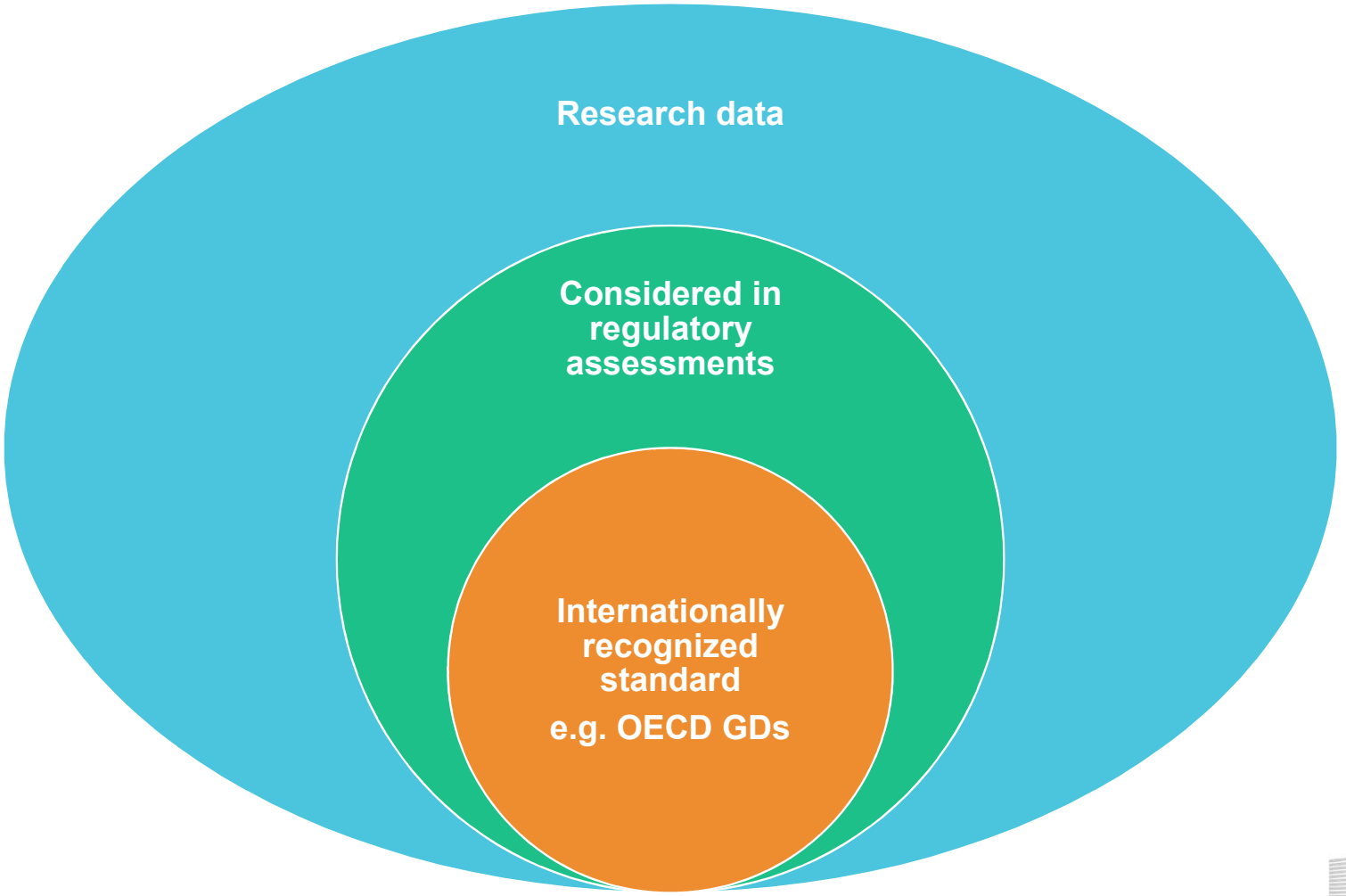
…. need to consider all available scientific data…



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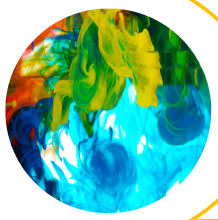

CSS – 1S1A

Workshop

Oct 2022

Ispra

WPHA project

Dec 2022 – June 2024

2 surveys

4 case studies

Webinar JRC-KI, SU

OECD GD

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OECD

Expert group of WPHA

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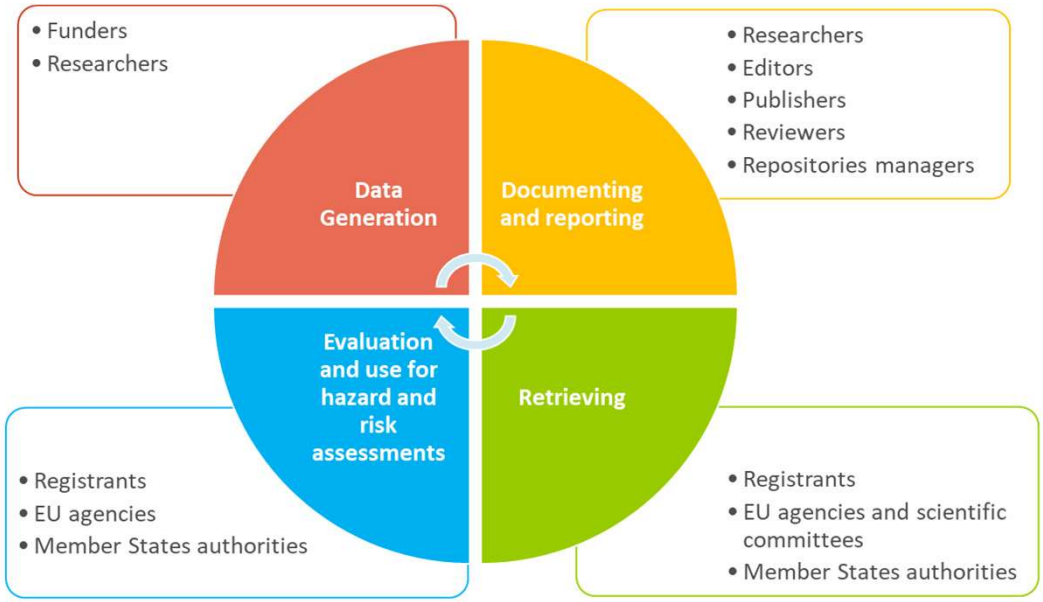
Guidance Document

1. **Production and reporting of non-standard data for regulatory consideration**
2. Principles and approaches for the identification, selection and evaluation of research data (incl. case studies)
3. Recommendations for harmonisation data evaluation, extraction and reporting



Webinar objectives

- raise awareness of the policy challenge and of the related OECD WPHA initiative
- collect inputs from researchers active in the development of good practice, reporting standards or data management solutions
- engage scientists in supporting the implementation of the guidance

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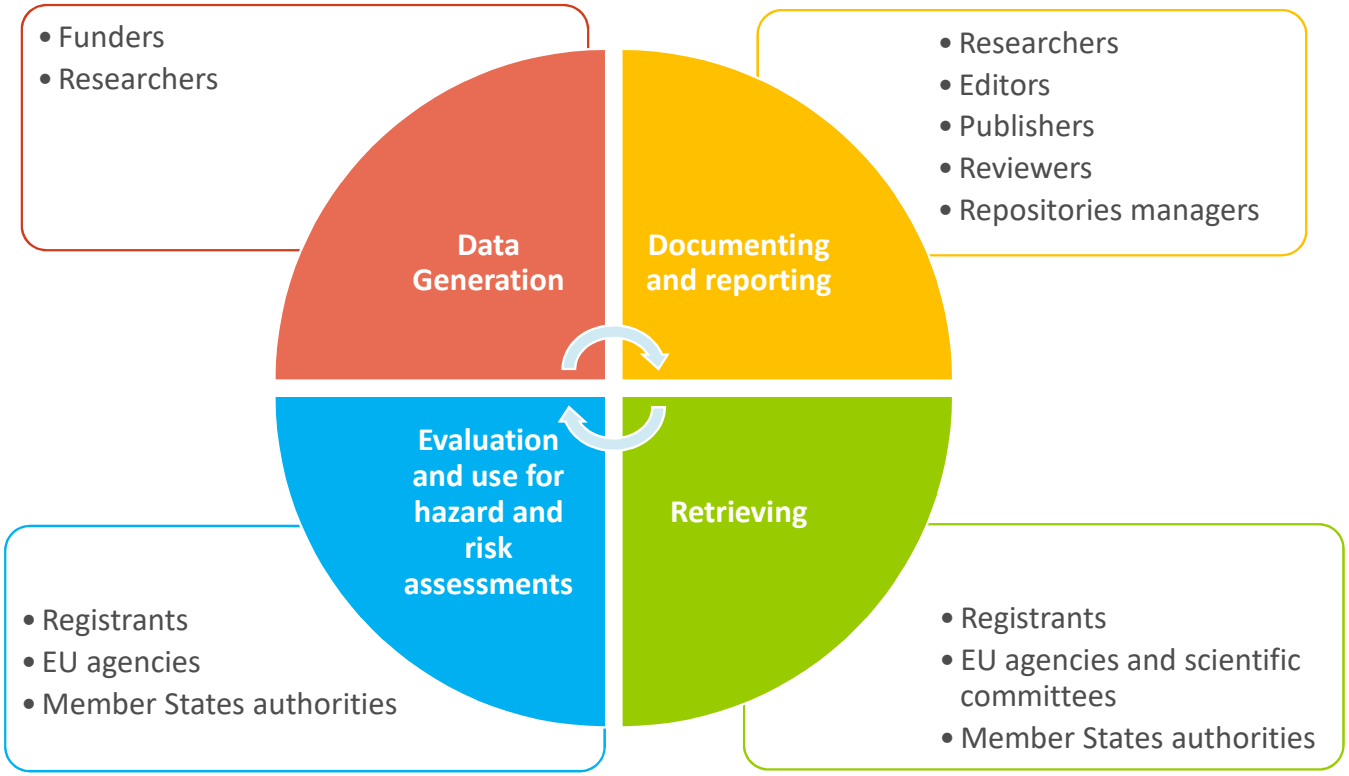
Extra slides

The life cycle of academic data



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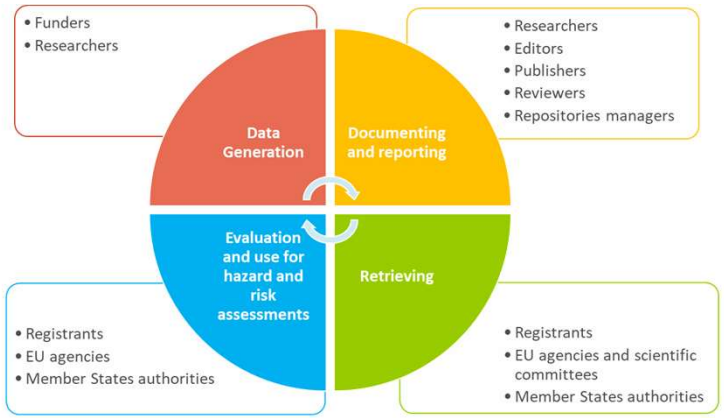
Desired impact

Researchers know what is expected for regulatory consideration and the available resources to implement good practice

Funders (e.g. DG-RTD) refer to GD when defining requirements in research calls



Journals (**publishers, editors, reviewers**) and data repository managers refer to GD to implement publication policy for increased regulatory impact

Assessors (**registrants, public authorities**) across sectors and jurisdictions share approaches and exchange outcomes of screening and evaluation workflows

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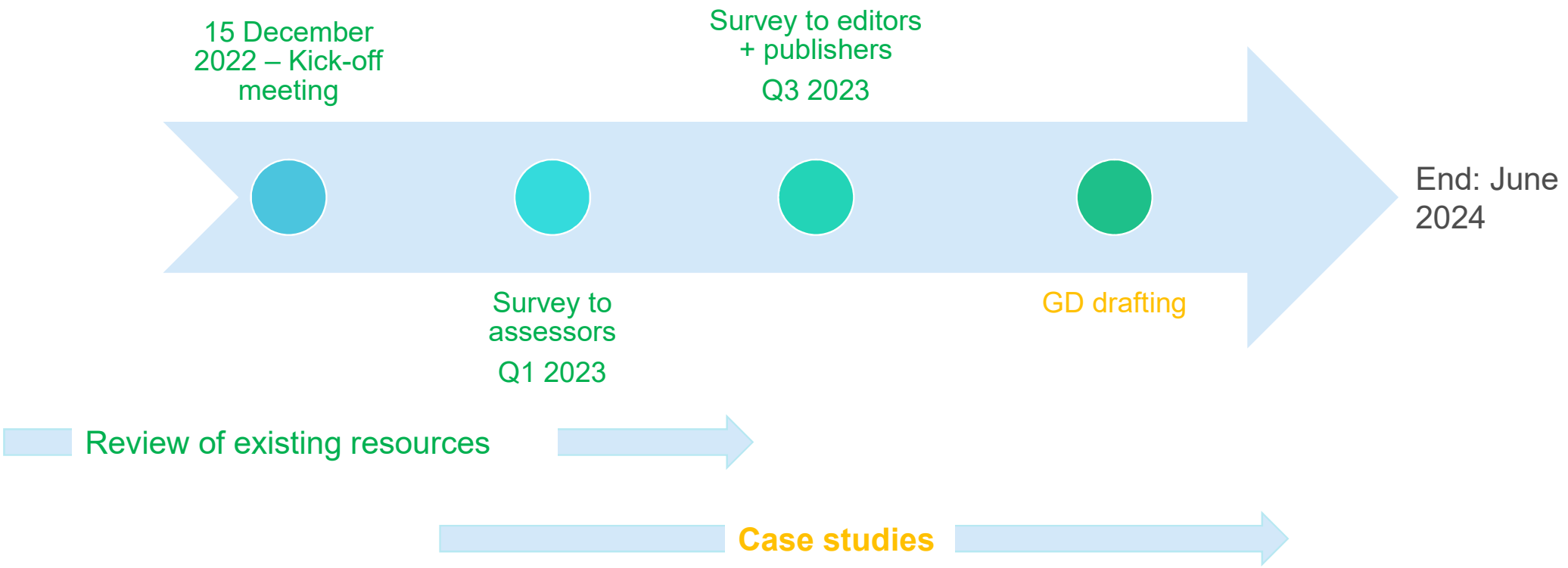
Proposed case studies

- Characterising human health evidence for 500+PFAS: interoperability of workflows (US EPA)
- Identification of an endocrine disruptor in the EU regulatory context (EC-JRC, SE Karolinksa Institute, EFSA)
- Harmonization of an evaluation system for the use of scientific ecotoxicity data in risk assessment (CH BAFU, DE UBA)
- Literature review by applicant for the Renewal Assessment Report (RAR) of fenamiphos (EFSA)

Project timeline



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Surveys

Use of Academic Data in the Regulatory Assessment of Chemicals

OECD_AcademicData

Target: assessors

Objectives

- Understand current practice
- Complete mapping of existing resources (GD, part 1)
- Consider assessor's needs and suggestions for the GD (part 2, incl. case studies)

Completed in Q2 2023 EU survey results (91 answers)

Publication of Academic Data for Regulatory Use

OECD-WPHA_Survey_Publication_Academic_Data_Regulatory_Use

Target: research funders, publishers, editors and data repository managers

Objectives

- Engage stakeholders in the initiative and especially in the Implementation of the GD

Completed in Q4 2023 EU survey results (16 answers)

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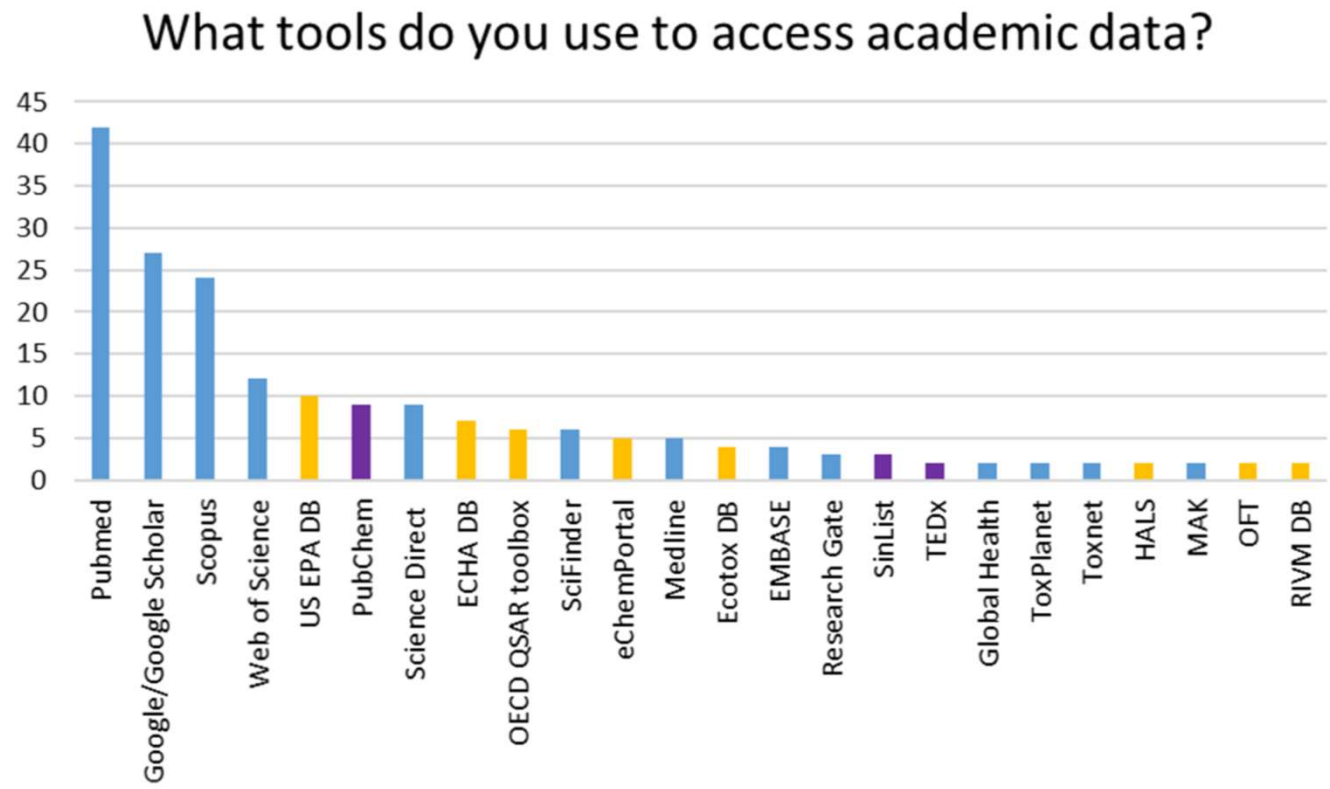
Survey to assessors



Bibliographic DBs / internet search

Regulatory databases

Other

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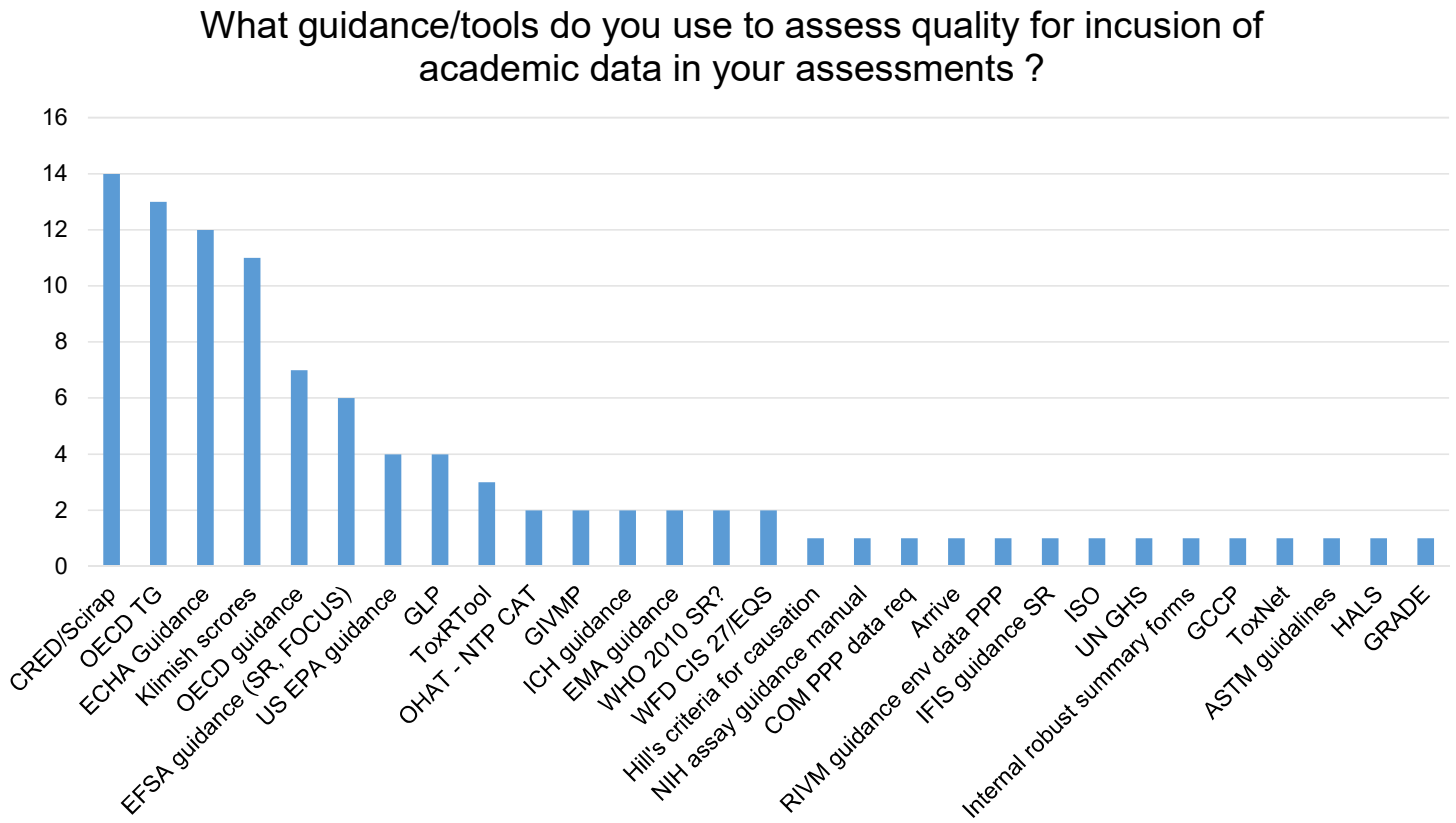
Survey to assessors



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