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Commercial v Academic Research Approaches to Reproducibility

Fiona Booth

Data Integrity & QA Programme Director

University of Bristol

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Pharma Experience

Clinical Trial Operations

- Clinical site monitoring
- Clinical trial management
- Clinical trial design
- Budget management & funding

Quality Assurance

- Clinical trial audits
- Quality system management
- Quality assurance strategy
- Vendor quality oversight

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Mentimeter

Have you worked for a pharma, biotech or other commercial research organisation?

0%

Yes

0%

No

Menti

HDRN

Choose a slide to present

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Mentimeter

What do you think makes research reproducible?

Menti

HDRN

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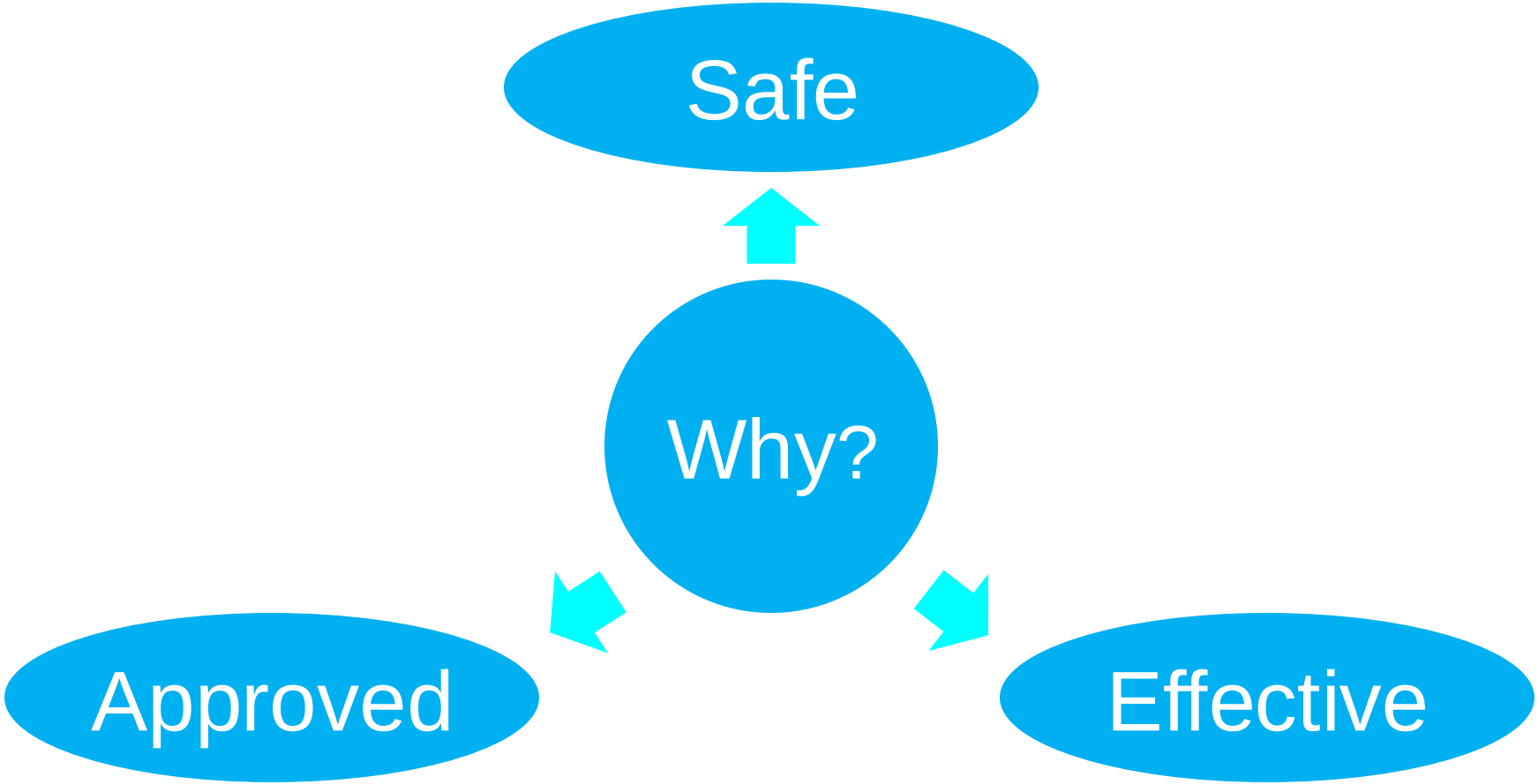
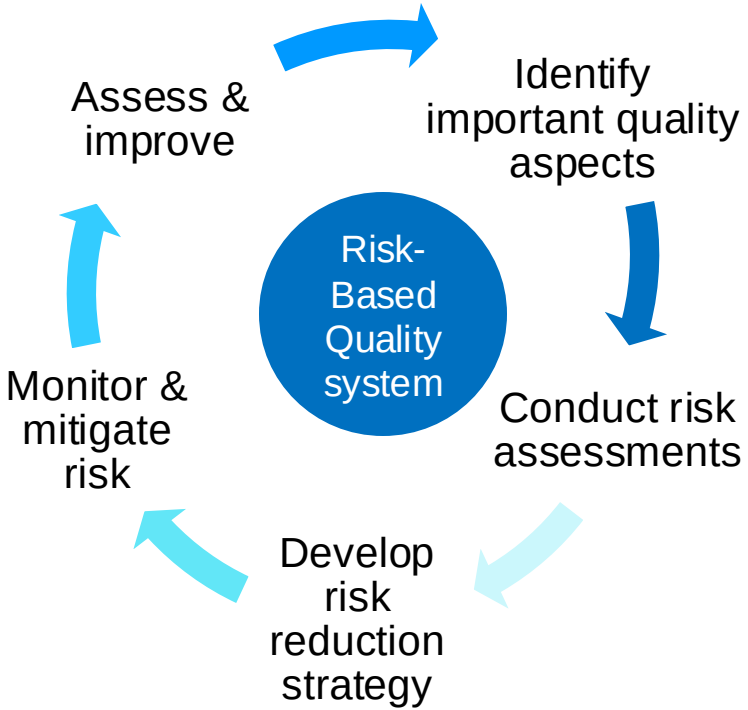

Safe
Why?
Approved
Effective

How?



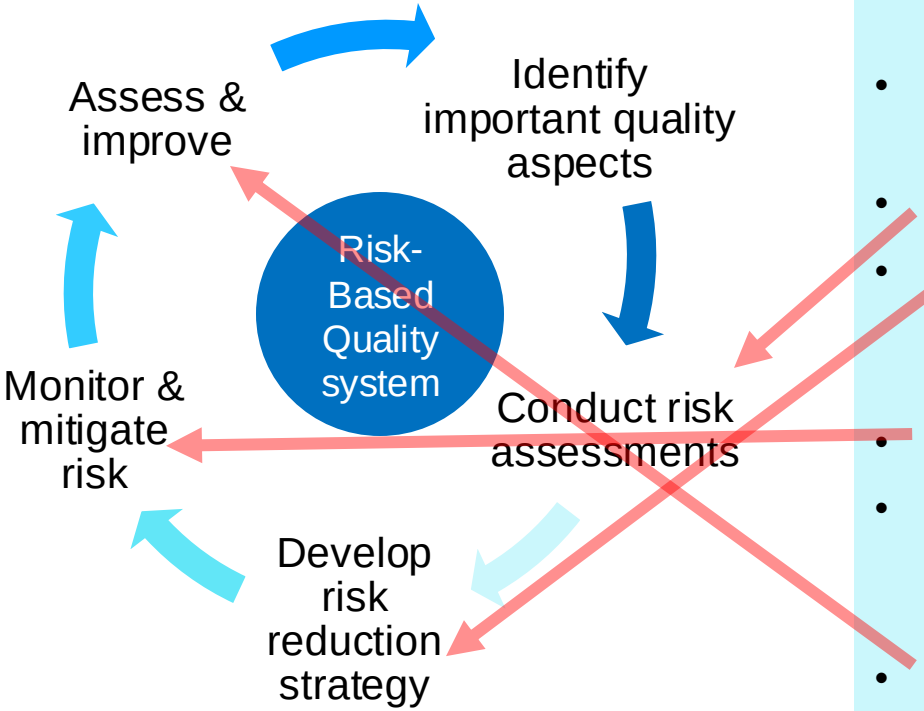
ALCOA

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate

But wait… what about ML/AI?

- Step 1: Define the question of interest that will be addressed by the AI model
- Step 2: Define the COU (Context of Use) for the AI model
- Step 3: Assess the AI model risk
- Step 4: Develop a plan to establish the credibility of AI model output within the COU
- Step 5: Execute the plan
- Step 6: Document the results of the credibility assessment plan and discuss deviations from the plan
- Step 7: Determine the adequacy of the AI model for the COU

FDA Guideline for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products, FDA Jan 2025 (Draft)



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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Transparency rule:

- Serious breach of Clinical Trial Regulation
- Temporary halt
- Unexpected event
- Urgent safety measure
- Corrective action
- Clinical study report

Clinical Trials

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Search clinical trials and reports > Search for clinical trials

In this page you can search for clinical trials. See Search tips for more information. If you would like to search for trials and show the results on a map you can do it here.

Search Criteria | Search results | Display options

Basic Criteria

Contain all of these terms:

Contain any of these terms:

Does not contain any of these terms:

No resulted reported yet

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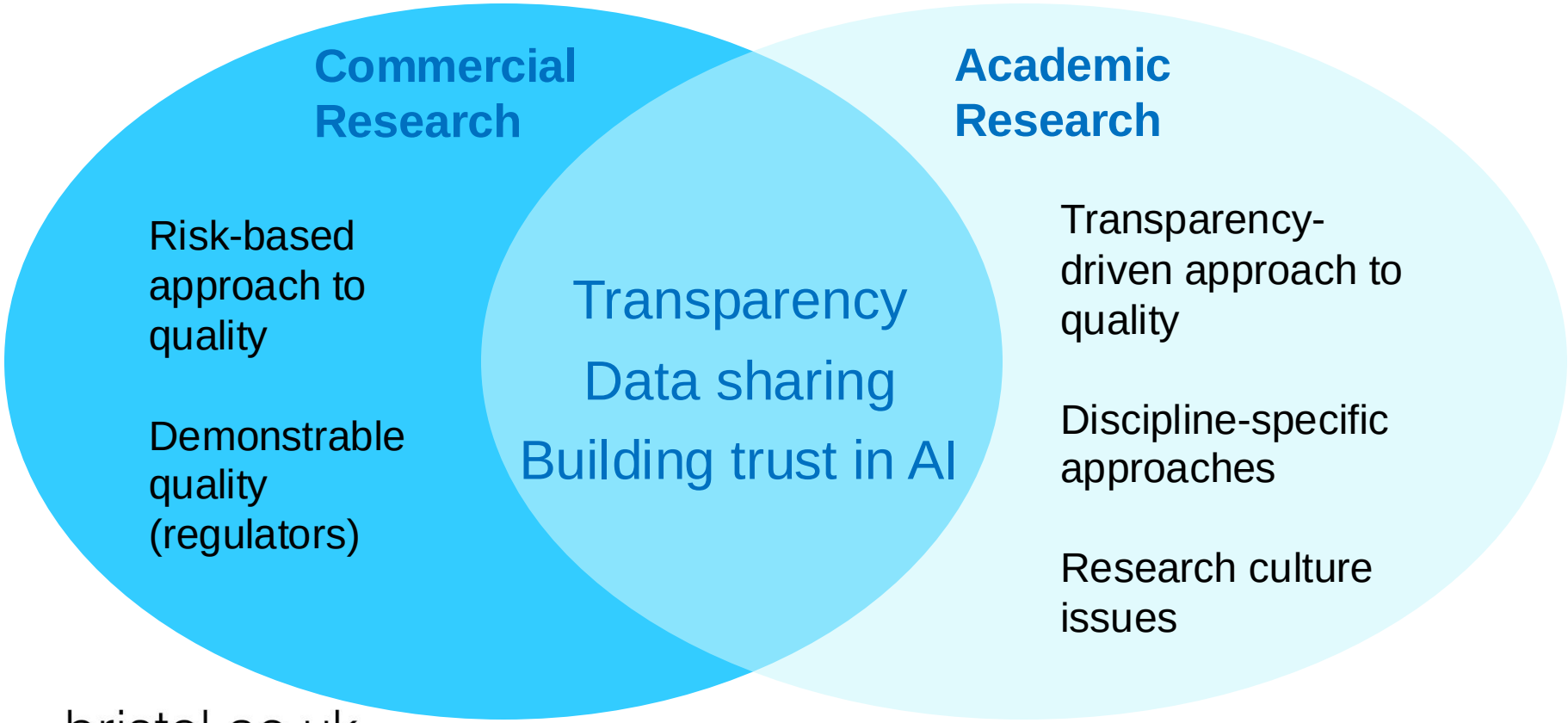
Use Cases for Data Science in Pharma

The Clinical Trial Anomaly Spotter (CTAS) is a powerful open-source tool for Central Statistical Monitoring that identifies outliers and anomalies efficiently and accurately in clinical trial time series

Tool that generates protocol templates based on historical trials by leveraging LLMs, data, and study documents from the Aggregate Analysis of ClinicalTrials.gov Database. the source code is freely available via Github

Protein structure prediction with multiple uses in rare disease drug development, antibiotic resistance, malaria vaccines, rotavirus, Parkinson's disease. Model is open source and available on Github

Reproducibility = Transparency?



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METARESEARCH GROUP

Would you like to be part of a community that aims to make research better?

Do you want to:

- expand your collaborative links for your research?
- learn how your research fits into growing funding opportunities?
- meet and involve new and broader stakeholders in your research?
- be part of a group that can help promote you and your research?
- meet like-minded researchers?

Join a growing group of meta-researchers at our launch event. We welcome all staff and PGRs. Professional Services and technical staff with an interest in improving research are encouraged to attend.

6 May 2025 10 - 12 Arts Complex G.H021

Come and give a lightning talk on your research (on research), or come along to listen and meet like-minded people. Delicious biscuits and refreshments will be provided!!

EMAIL US TO REGISTER YOUR INTEREST OR REQUEST A LIGHTNING TALK SPOT:
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Reproducibility by Design

Replicability and reproducibility of academic research outputs are at an unacceptably low level across many disciplines. Herein, you can find guidance, tools and resources to help improve research quality to promote higher standards of replicability, reproducibility and resulting applicability and impact of your research.

Scroll down or use links on the left to explore modules covering a range of content. Alternatively scroll down to the bottom and browse content relevant to different research stages.

REPRODUCIBILITY
BY DESIGN

https://uob.sharepoint.com/teams/grp-ReproducibilitybyDesign

References

- International Council on Harmonisation Guideline on Quality Risk Management Q9, 2005 ICH E10
- Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products, Draft Guidance for Industry and Other Interested Parties, FDA January 2025
- Impala Clinical Trial Anomaly Spotter GitHub - IMPALA-Consortium/ctas: Time Series Outliers and Anomalies
- Lindus Health Powers Data-driven Trial Decisions with the Aggregate Analysis of ClinicalTrials.gov (AACT) Database, Lindus Health Leverages CTTI's AACT Database
- AlphaFold3 GitHub - Ligo-Biosciences/AlphaFold3: Open source implementation of AlphaFold3

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ANY QUESTIONS?

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