

**EUROPE  
BIOBANK  
WEEK**

SEPTEMBER 13-16, 2016  
VIENNA - AUSTRIA

**Emily Kirby: "P3G DataTrust – Developing a DataTrust (DT) Service for Personalized Medicine Research"**



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# P<sup>3</sup>G DataTrust – Developing a DataTrust Service for Personalized Medicine Research

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*Vienna, Austria*

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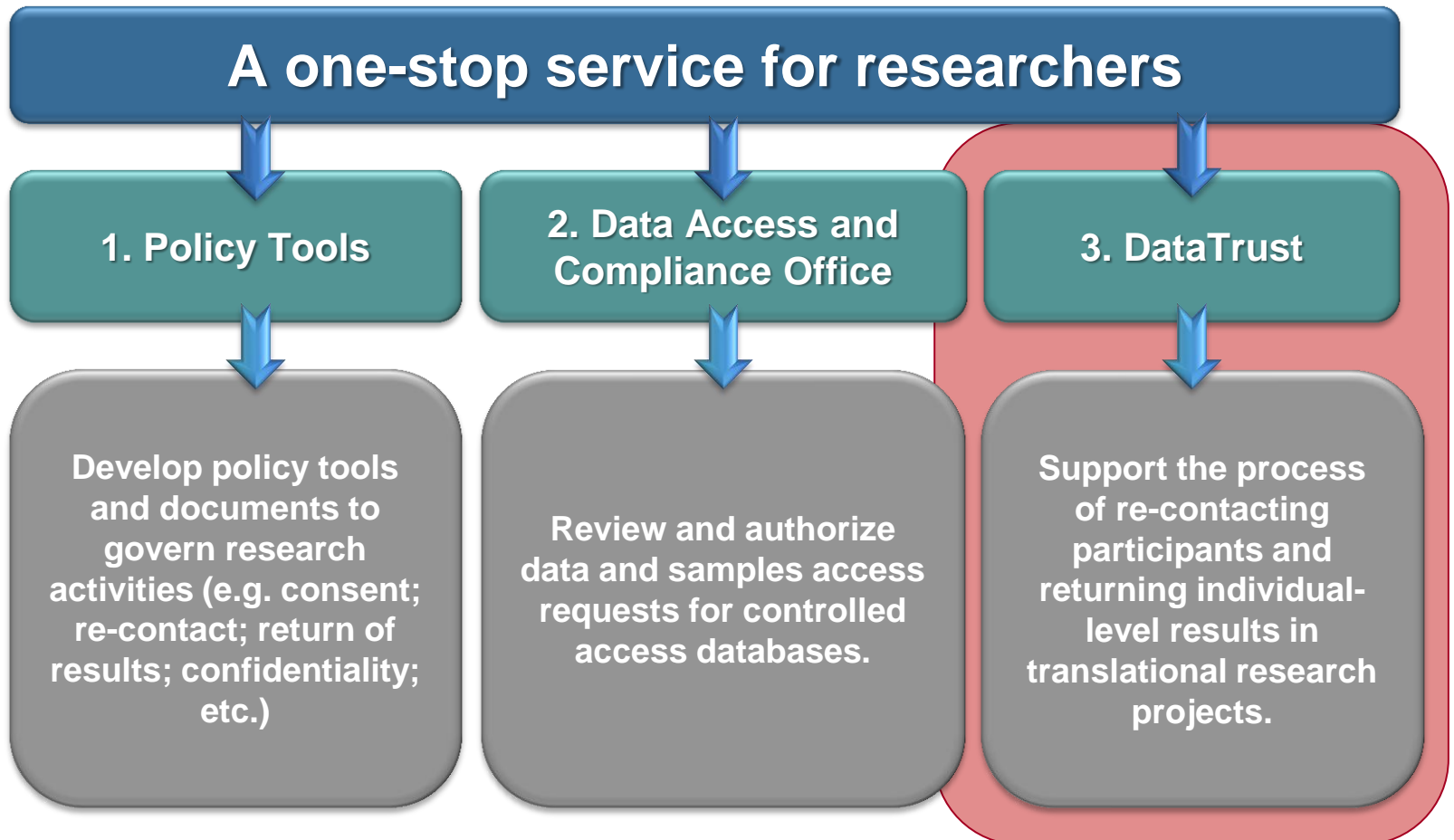


# What is P<sup>3</sup>G?

- An international Consortium which supports health research networks and projects;
- Dedicated to the development of the policy infrastructure for biobanks, research databases and other similar research initiatives;
- Through our tools, support and networks, we help the international research community to prepare and implement effective policy strategies;
- A network of more than 560 individuals and institutions from over 40 countries.



# P<sup>3</sup>G-IPAC Services





# Background

- Due to concerns surrounding the secure return of clinically significant results to research participants, the Public Population Project in Genomics and Society (P<sup>3</sup>G) developed a framework to enable the implementation of a DataTrust service.
- In collaboration with scientific, clinical and communications committees, this service supports, when appropriate, the **process of returning individual-level research results in the context of personalized medicine research.**

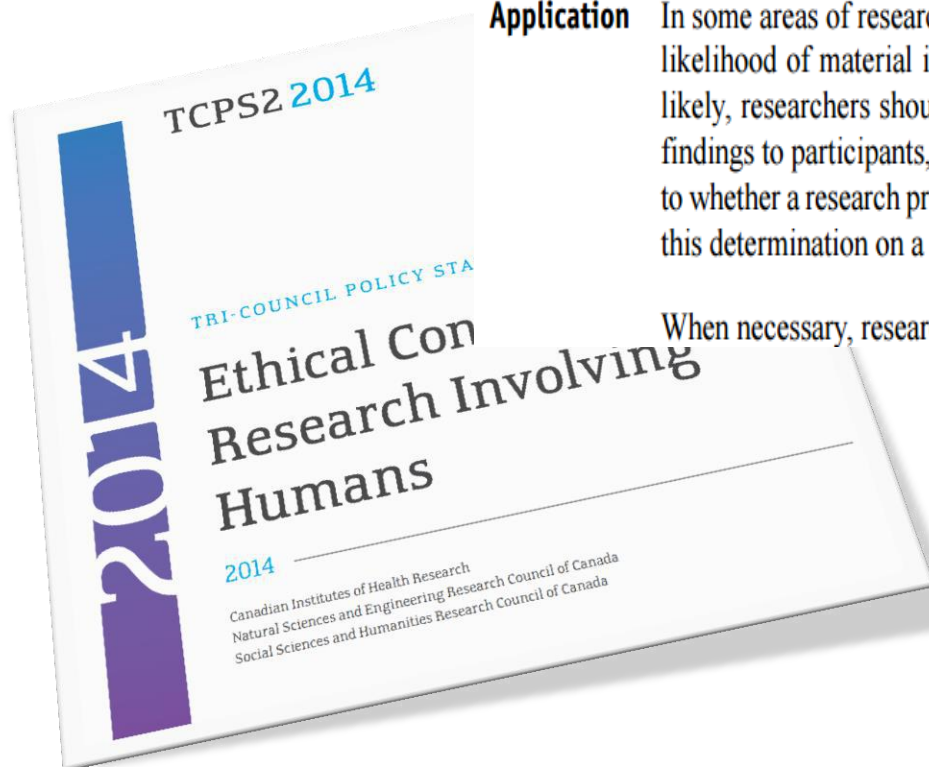


# Why the DataTrust framework?

**Article 3.4** Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.

**Application** In some areas of research, such as medical and genetic research, there is a greater likelihood of material incidental findings. When material incidental findings are likely, researchers should develop a plan indicating how they will disclose such findings to participants, and submit this plan to the REB. If there is uncertainty as to whether a research project warrants such a plan, researchers and REBs can make this determination on a case-by-case basis.

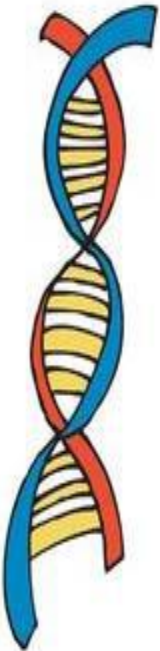
When necessary, researchers should direct participants to a qualified professional





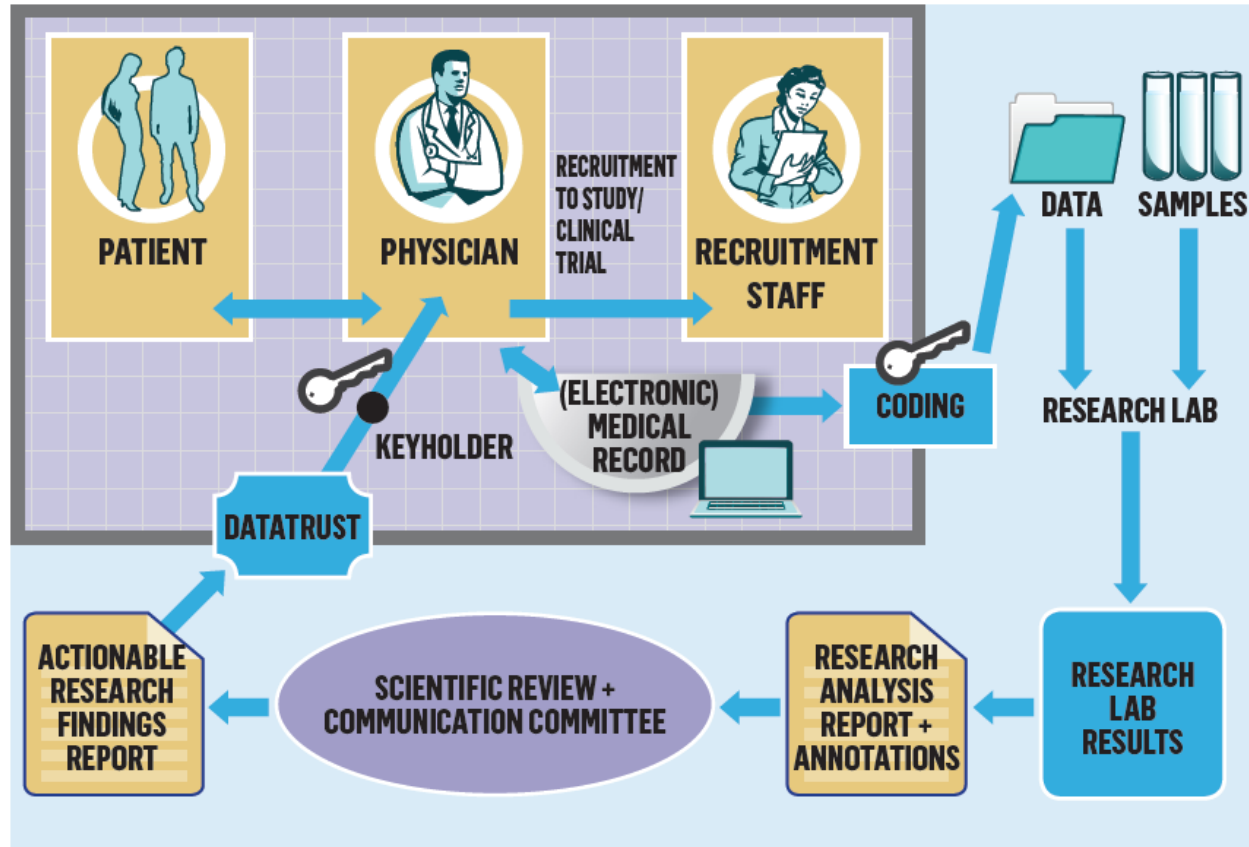
# Why the DataTrust framework?

- Context matters!
- Personalized medicine research projects which anticipate finding medically actionable results and returning returning results (ex: therapeutic optimization, diagnosis, PGx, etc.)
- Non-uniform consents.





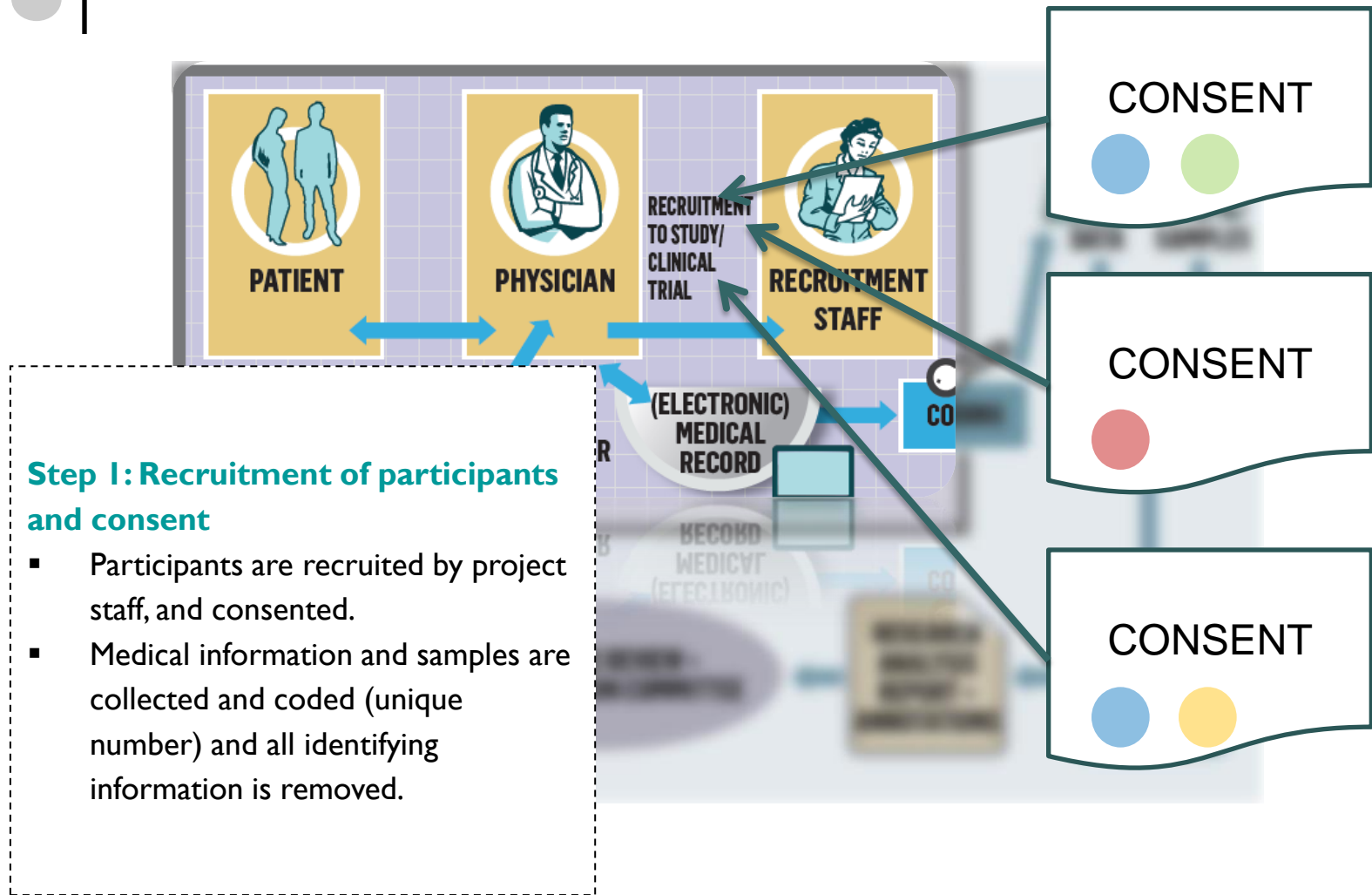
# DataTrust Implementation Framework







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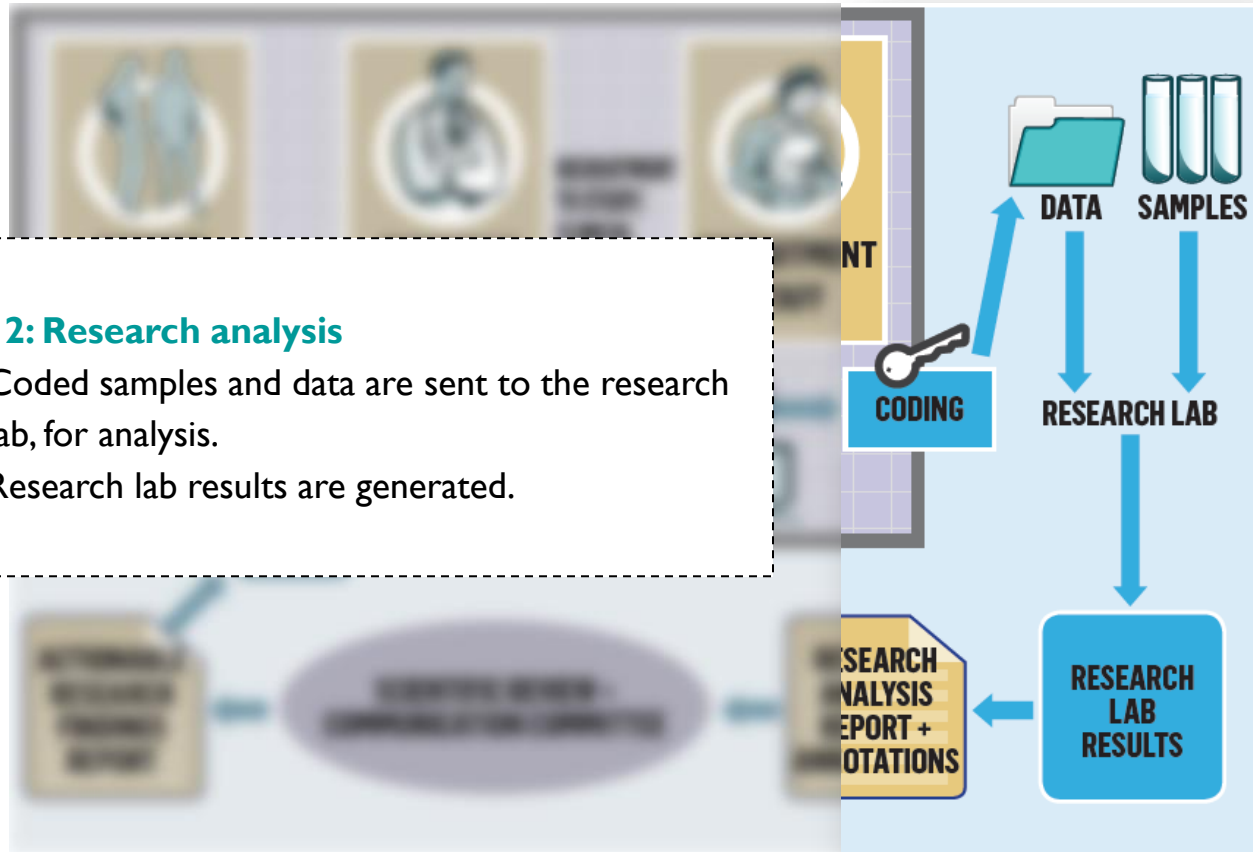




# DataTrust Implementation Framework

## Step 2: Research analysis

- Coded samples and data are sent to the research lab, for analysis.
- Research lab results are generated.

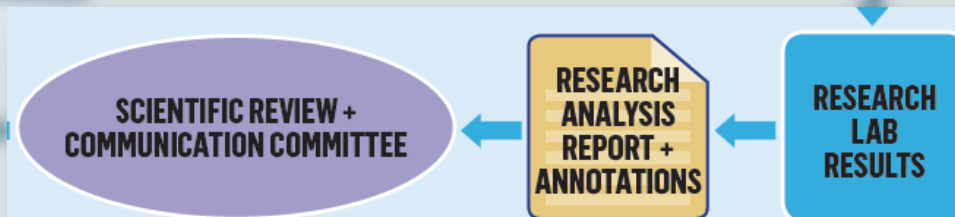




# DataTrust Implementation Framework

## Step 3: Scientific assessment of research analysis report and annotations

- The Scientific Review Committee examines the research lab report and makes recommendation on returning results based on **scientific validity, clinical utility** and **clinical significance** (medical actionability).
- The Communication Committee prepares educational and explanatory material to accompany the return.

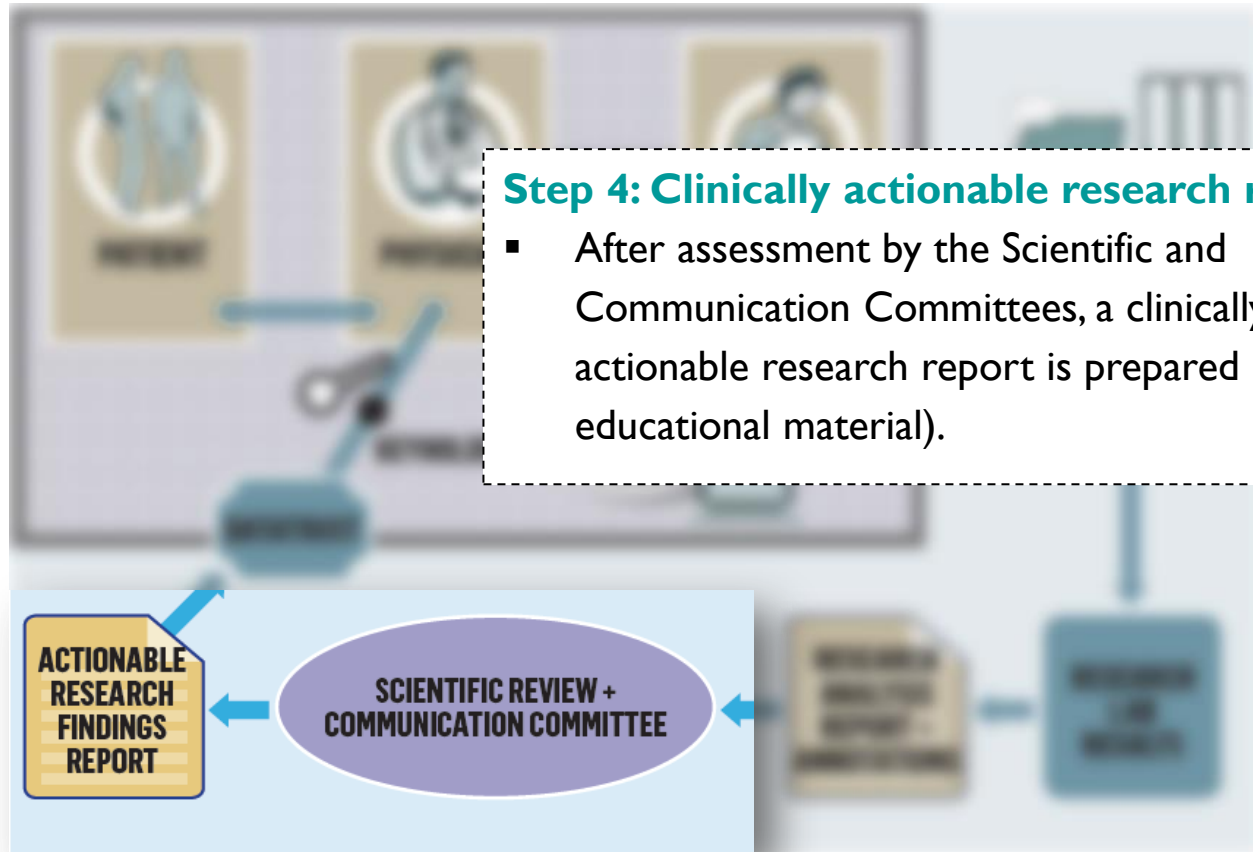


Category	Item 1	Item 2	Item 3	Item 4	Item 5
Group 1	Green	Yellow	Red	Green	Red
Group 2	Green	Yellow	Red	Green	Red
Group 3	Green	Yellow	Red	Green	Red



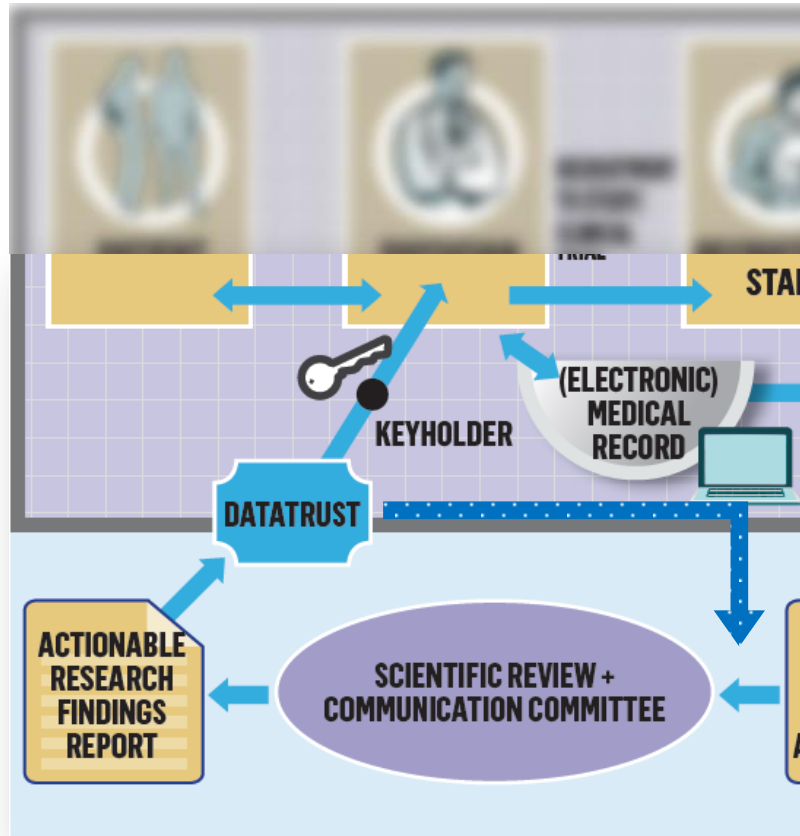


# DataTrust Implementation Framework





# DataTrust Implementation Framework



## Step 5: DataTrust ethical due diligence

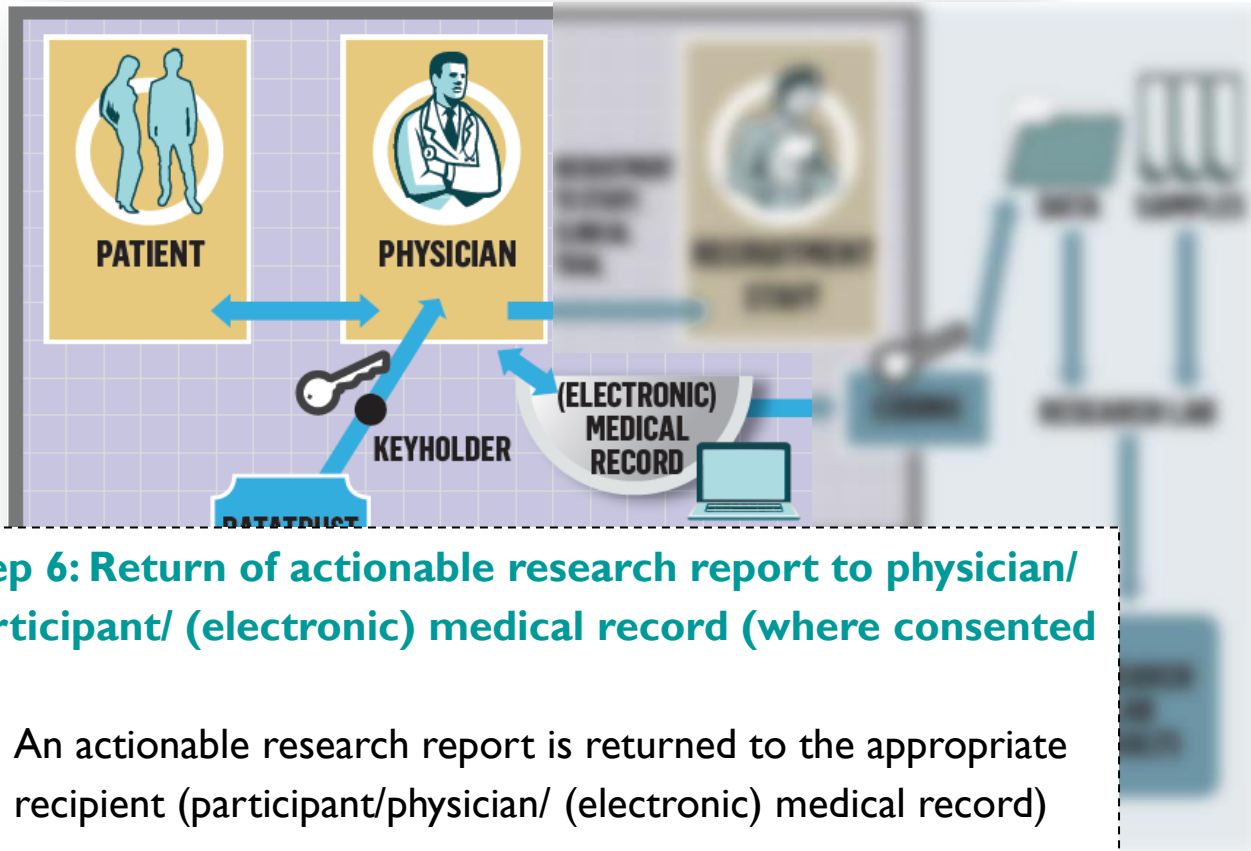
- The DataTrust conducts an ethical due diligence, and acts as a final “gatekeeper” for the return of individual results.
  - For example:
    - ✓ Authorize keyholder to re-link code to personal information;
    - ✓ Verify that appropriate consent was signed;
    - ✓ Verify that return of results was accepted;
    - ✓ Verify that a physician to report results to is listed;
    - ✓ Verify that the actionable research report is complete;
- Etc.

**AUTHORIZE / REFUSE THE RETURN OF RESULTS**





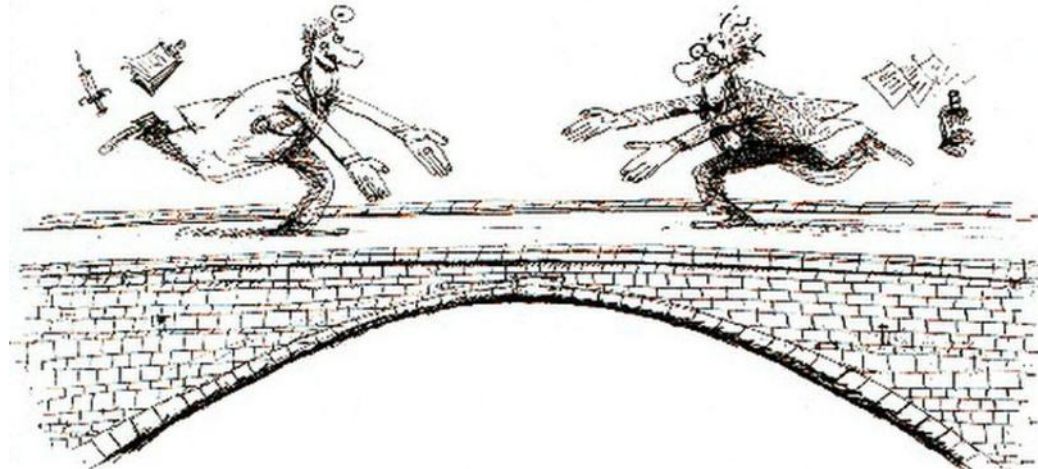
# DataTrust Implementation Framework





# DataTrust Implementation Framework

- **Opportunities of the proposed approach**
  - DataTrust provides an ethical “due diligence” gatekeeping function;
  - Scalable and customizable framework, applicable to different contexts;
  - Alleviates the research team from this final verification task by establishing clear roles and responsibilities.





# Acknowledgements

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Thank you for your attention!



P<sup>3</sup>G: [www.p3g.org/ipac](http://www.p3g.org/ipac)



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