Clinical development & Analytics

What has changed? Why is data now an asset?

PSI Conference Webinar: In memory of Sally Hollis (former SIG Chair)

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June 9, 2020

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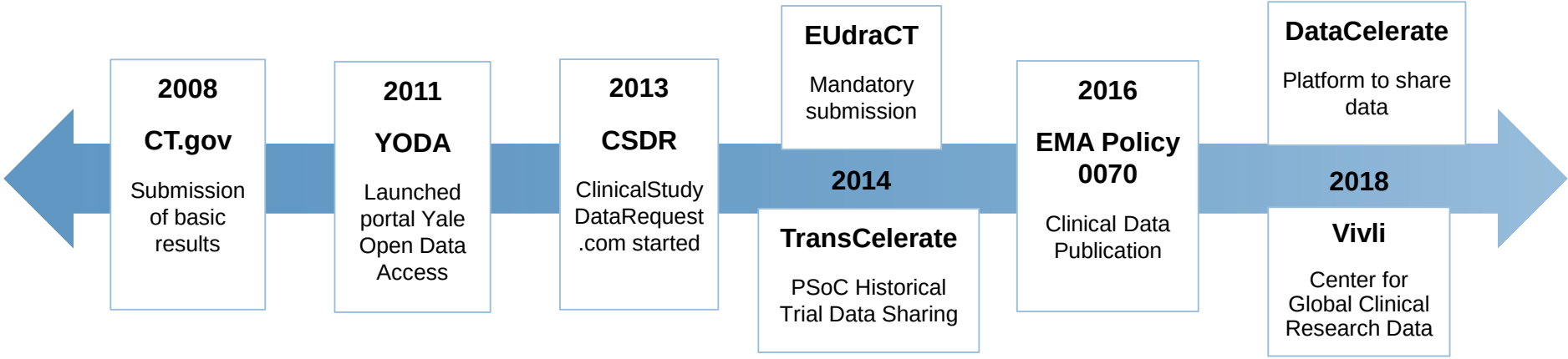
Agenda

1. The evolution of data sharing and data access
2. Challenges we need to consider in re-use of data
3. Potential solutions for these challenges
4. Promoting data as an asset for external use
5. Promoting data as an asset for internal use
6. A few thoughts on the impact of COVID-19

The evolution of data sharing and access

- Over the last decade and longer we have seen an increase in various efforts regarding access to data and information from clinical trials
- A few key milestones



- 2020 will COVID-19 Pandemic expedite efforts?

What has driven the evolution of data sharing?

Pharma Reputation	Scientific Research	Technology and Data
• Bad Pharma (B. Goldacre 2013) • Journals requesting data • Reproducibility crisis in research	• Long and ever increasing costs of drug development • Companies internally need to maximize use of their data and generate more insights	• Compute power is no longer a barrier • ML and AI for big data • Interest in many newer data modalities omics, sensors, images and IoT

Data has become an asset with huge potential for re-use to advance science

Challenges we need to consider in re-use of data

- Ethical considerations : Data collected in clinical trials is personal sensitive information and must be used in accordance to the Informed Consent the subject completed
- Legal and Data Privacy considerations: New GDPR (General Data Protection Regulation) taken up in EU but often country specific interpretations
- Good scientific research : scientifically sound reproducible research
- Buisiness sensitivity: primary use is for registration of new medicines for patients so any re-use needs to take timing of this into account

Underpinning these considerations is the culture change in viewing data as an asset

Challenges and possible solutions we need to consider in re-use of data

- Ethical considerations : Data collected in clinical trials is personal sensitive information and must be used in accordance to the Informed Consent the subject completed
  - Does informed consent allow for additional research? – is it all patients or a subset of patients?
  - Anonymized data are no longer personal – should we anonymize?
  - With anonymization what do we lose in terms of data utility?
  - What method of anonymization – risk or rule based, other methods?
  - What is the role of synthetic data?
- Legal and Data Privacy considerations: New GDPR (General Data Protection Regulation) taken up in EU but often country specific interpretations
  - GDPR potentially allows more flexibility for additional research : *"Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations." Consideration 50 + Art. 5.1 (b) GDPR*
  - Also included for patients the right of erasure/ right to be forgotten (applicable to non-anonymized data)

Challenges and possible solutions we need to consider in re-use of data

- Good scientific research : scientifically sound reproducible research
  - Ensuring data and information – includes plans, data and results are FAIR (Findable, Accessible, Interoperable and Reusable)
  - Ensures efficiency in terms of work/exploration not being redone by many users at different times
  - Large data pools – we will find interesting signals but are they real or not – scientific reproducibility crisis – we need to be diligent
- Business sensitivity: primary use is for registration of new medicines for patients so any re-use needs to take this into account
  - Re-use of data should be on locked studies
  - Depending on stage of the program will indicate the level of involvement of the project team in the research (planning, execution and results)
  - Access and re-use will also depend on the scientific question of interest
  - Is there any Commercially Confidential Information or research needing to be taken into account?

What is Novartis doing to promote data as an asset (externally)?

- Novartis is part of https://www.clinicalstudydatarequest.com/Default.aspx and so external researchers can request data through this portal.
  - Accessible trials are post approval in major HA
  - Phase II-IV studies and data are anonymized using risk based anonymization
  - Researcher submits proposal
  - Data shared in secure environment and limited access time
  - Results shared

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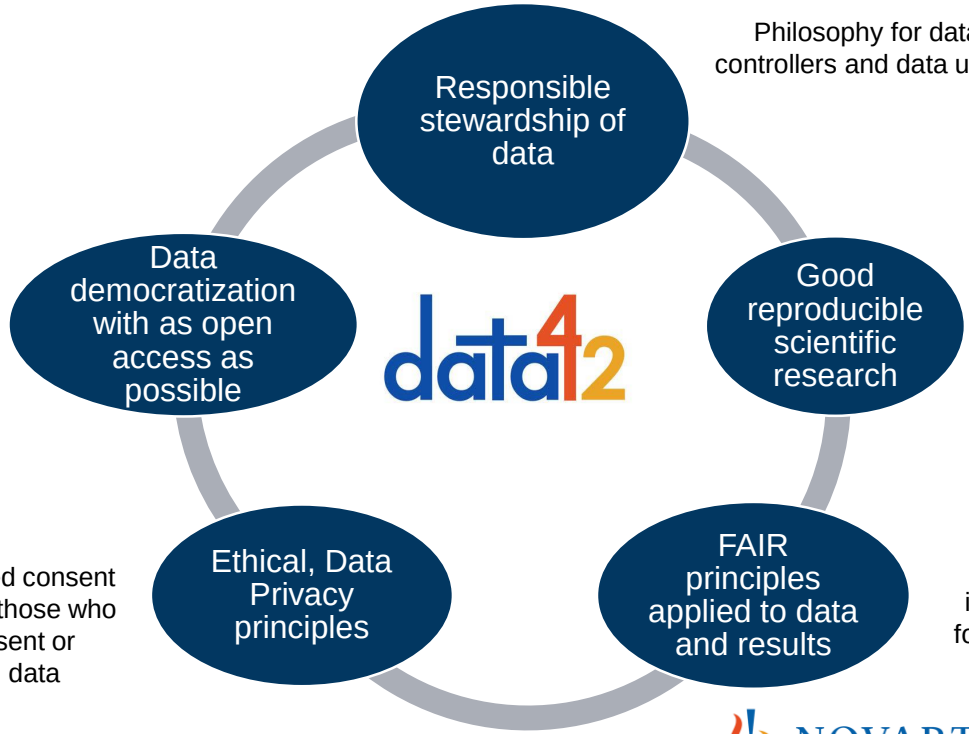
What is Novartis doing to promote data as an asset (internally)?

- Internally for re-use of data – project data42 which aims to facilitate frictionless access to Research and Development data

"We have around 2 million patient-years of data in our system. This is the crucial asset which will be instrumental going forward as we apply artificial intelligence tools to sift through the data and find hitherto unknown correlations between drugs and diseases."

- Use this wealth of data to help plan more efficient drug development programs through using historical data, understanding diseases better and performing virtual proof of concept studies

How are we taking all the challenges of data re-use into account in data42?



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Impact on data access and re-use under the COVID-19 pandemic

- TransCelerate BIOPHARMA INC. — ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

  Utilizing its DataCelerate® platform to share Member Company control arm data from ongoing and planned COVID-19 clinical studies, as well as data from past studies in related diseases or patient populations

- biobank uk — Improving the health of future generations

  Crucial new data on the health of 500,000 UK Biobank participants are being made available to scientists tackling the COVID-19 emergency. Results of COVID-19 tests for UK Biobank participants (both positive and negative test results) are provided by Public Health England (for participants resident in England).

- OpenSAFELY

  A new secure analytics platform for electronic health records in the NHS, created to deliver urgent results during the global COVID-19 emergency. It is now successfully delivering analyses across more than 24 million patients' full pseudonymised primary care NHS records, with more to follow shortly. All our analytic software is open for security review, scientific review, and re-use.

Impact on data access and re-use under the COVID-19 pandemic

- HDRUK Health Data Research UK

  Co-ordinate and connect national data science driven research efforts related to COVID-19; Accelerate access to UK-wide priority data relevant to COVID-19 for research

- Vivli CENTER FOR GLOBAL CLINICAL RESEARCH DATA

  Specific portal for COVID-19 trials and data

- Many other platforms and hackathons/data challenges initiated
- Do we see a change in mindset with regard to sharing and access and how do we learn from this?

Conclusion

- The potential is huge with regard to the impact on advancing science
- Cross-functional effort with many complexities
- Keep good scientific research at the center of how we do this – articulate the value for patients and society/public health while recognizing and managing the data privacy and ethical concerns
- Work together as a community and share experience, learning from critical situations such as COVID-19