Return of Results
Aggregate and Individual

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March 18, 2019

Disclaimer

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Session III: Post-Trial Communication & Engagement

1. Evolving landscape
   - Overcoming challenges and progressing solutions
   - Working as part of multi-stakeholder consortia
   - Seeking to progress change internally and externally
2. Plain Language Summaries
3. Individual Return of Results

Takeda, Pfizer and others have been partnering over the past five years with various organizations including:

- Harvard Multi-Regional Clinical Trial Center
- TransCelerate BioPharma
- Health Research Authority Task Force on European Union Clinical Trial Regulation
- Layperson Summary Guidance
- Patient Data Access Initiative
- Supporting individual Public-Private Partnerships

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Plain Language Summaries

Plain Language Summaries

- Make results accessible to study participants and general audience
- Aggregate results of a single trial written in plain language
- Explain technical terms and complex concepts in simple language

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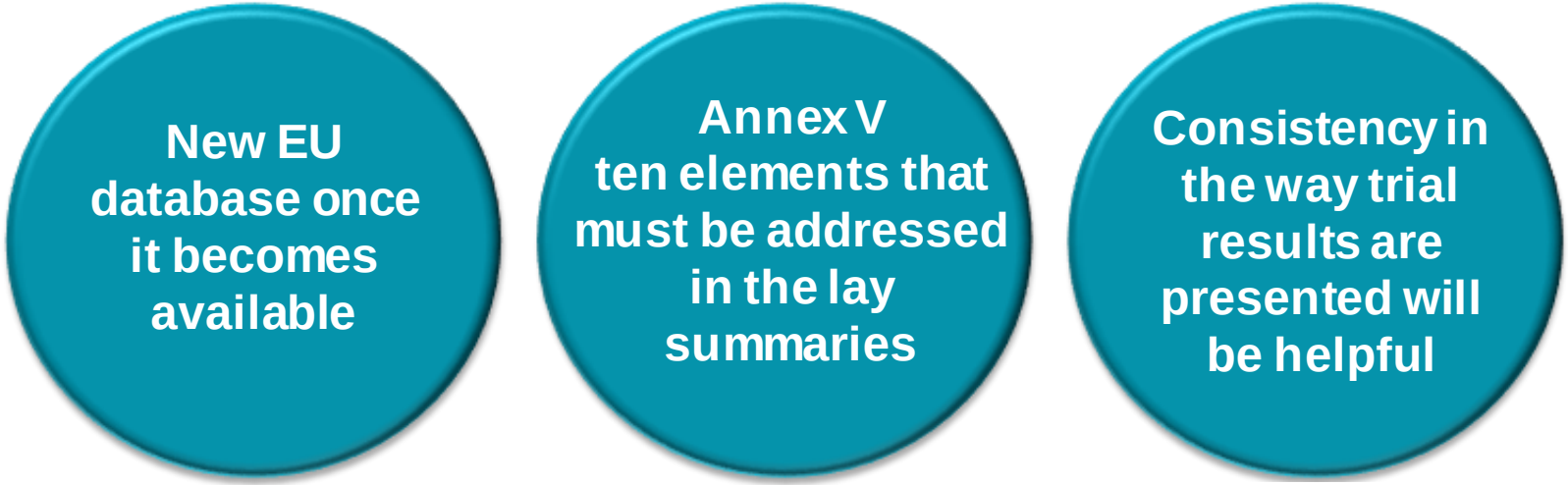
Plain language summaries

EU Clinical Trials Regulation 536/2014 (Article 37) (EU CT Regulation)



Effective from 2020

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Working Collaboratively

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

- Harvard MRCT*
  - MRCT Return of Results Guidance Document, Version 3.1, December, 2017
  - Return of Aggregate Results to Participants Toolkit Version 3.1

Draft Plain Language Summary Guidance Document Submitted to FDA, September 2017

TransCelerate BIOPHARMA INC.
ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

- TransCelerate BioPharma Inc**
  - Recommendations for Drafting Non-Promotional Lay Summaries of Clinical Trial Results EU CTR Task Force and formal Guidance
  - Layperson Summaries of Clinical Trials: An Implementation Guide

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* Accessed on March 15, 2019 at https://mrctcenter.org/blog/projects/return-of-results-to-participants/

** Accessed on March 15, 2019 at: http://www.transceleratebiopharmainc.com/wp-content/uploads/2015/04/TransCelerate-Non-Promotional-Language-Guidelines-v10-1.pdf

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Remaining barriers/challenges

- Sponsors need to develop summaries and method of distribution
- Pre-publication concerns– no clear position from journals
- Need for clear FDA guidance
- Role of Independent Review Board (IRB)
- Potential to be seen as promotional

"**84%** of Investigator/Physicians agree aggregate results should be shared with patients → **44%** have never shared with study participants"
Harvard MRCT Survey

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Return of Individual Results

"I don't think it is just an opportunity - I think it is an obligation - an unmet obligation that pharma disseminate updates on the drug and on your trial."

Patient, US

Understanding the landscape

TransCelerate Survey: Patient Perspective*

Over 3,000 patients surveyed across 36 countries - 2017

83%
The majority of patients **want their lab/test results**

68% want to know whether they received study drug or placebo

Regulatory changes

EU Clinical Trials Regulation 536/2014 (Article 37) (EU CT Regulation)

Key legislative considerations

HIPAA, CLIA, GDPR,

California Privacy legislation

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*Accessed on March 15, 2019 at: http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/11/What-do-Patients-Want-Visualization.pdf

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Return of individual results to participants

Consensus Study Report*

A landmark in the individual return of results space providing recommendations for the US, July 2018

*Accessed on March 15, 2019 at: http://nationalacademies.org/hmd/Reports/2018/returning-individual-research-results-to-participants.aspx

Understanding the value of accessing Clinical Trial Data / Results

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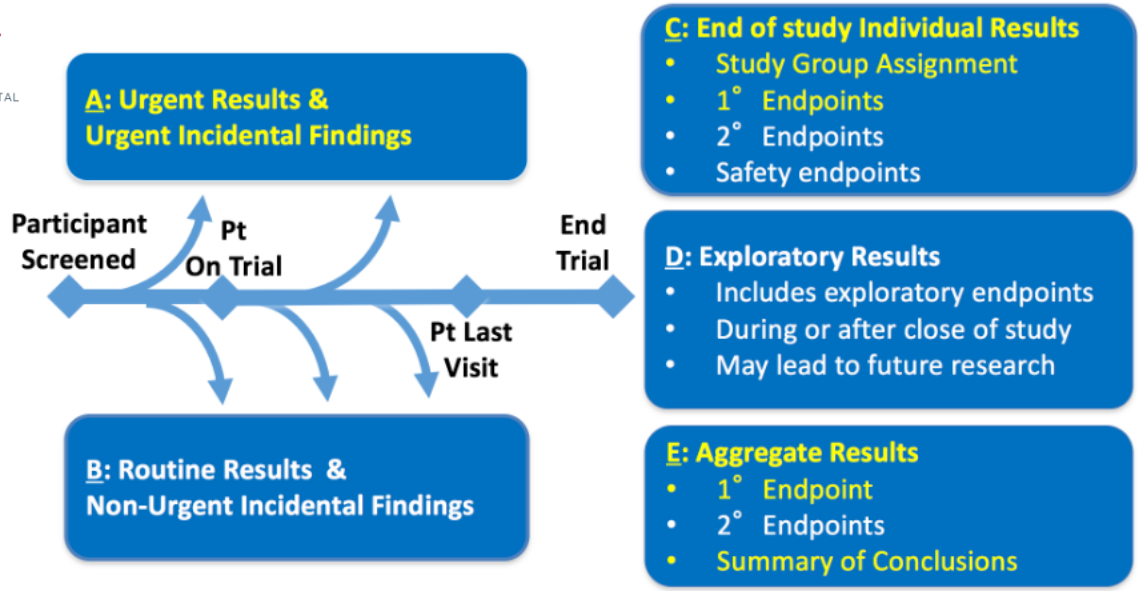
Gaining clarity on Individual Return of Results – what & when

- Harvard MRCT*
  - Return of Individual Results to Participants Recommendations Document Version 1.2 (Guidance), November 2017
  - MRCT Return of Individual Results to Participants Toolkit Version 1.2 (Toolkit), December 2017



Data types recommended for return, at a minimum, are highlighted in yellow

*Accessed on March 15, 2019 at https://mrctcenter.org/resources/?project=return-of-individual-results

Working with PDAI

:

To enable trial participants to access their data in a responsible manner that is standardized across pharmaceutical companies.

A collaboration of research sponsors dedicated to the return of individual research results

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PDAI - Working to solve the follow-up challenges facing patients, sites and investigators

Patients

Patients surfaced the following pain points regarding post-trial follow-up:

- A desire for **trial results** communicated promptly upon completion of the trial
  - Personal
  - Aggregate
- A desire to know which **trial arm** (experimental vs. standard of care/placebo)
- A greater sense of **closure** and **appreciation** from trial team reflected in clinical trial follow up

Primary Investigators & Nurse Coordinators

Investigators and coordinators mirror patients in the patient request for trial results, however, the following barriers arise:

- Primary investigators and nurse coordinators **often do not know trial results themselves** until they are published
- Trial results, between writing and peer review, **are published a significant amount of time after trial completion**
- Patients often ask what trial arm they were on, however **the study team is often not informed during or after the study**

"Trial results are published and released to the public typically over 1 year after trial completion. At this point, most patients have moved on; Oftentimes we do not know or ever find out trial arm of specific patients."

– Coordinator, US

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Patients are in control

- Protect patient privacy and autonomy by ensuring patients only receive the data they wish to

Responsibly share information

- Return data in a timely manner and withhold only the information needed to maintain trial integrity and comply with regulations

Not just data, information

- Provide context so patients can understand their data

Singular intention

- Create a consistently positive patient experience that remains adaptable to each sponsor's unique context

Seamless sharing

- Minimize burden on sites, investigators and patients

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Innovative Medicines Initiative (IMI) Health Outcomes Observatories

New platform to empower patients to contribute their outcomes data in a standardized way via digital tools to create transparency of health outcomes for Patients, HTAs and HCPs.

Benefits to Patients :

Collect standardized Patient Generated Data and PROs

Value Based Healthcare

Improved Patient Care & Outcomes

Project Partners:

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abbvie

NOVARTIS

Pfizer

SANOFI

Lilly

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Future focus: Evolving landscape toward Individual Return of Results

- Need for regulatory harmonization
- Address conflict of laws
- Consistency in IRB approach
- Change organizational culture internally & externally
- Develop vendor capabilities
- Further understand patient perspectives
- Conduct pilot studies
- Share learnings and best practices

Communities Collaborating

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