Beyond Traditional Clinical Trial Patient Data

Innovations and Operations

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Inspired by **patients.**
Driven by **science.**

Agenda

1. Traditional clinical patient data
2. “New” clinical patient data – Innovations
3. Beyond patient data – Operations
4. Opportunities and obstacles

Our company in a nutshell

- Global biopharma company
- Solid science heritage
- Revenue €5.8B*
- Sustainability as business approach
- Listed on Euronext Brussels

Our areas of focus

- Neurology
- Immunology

Our World

- Presence in 36 countries*
- 3,7M patients positively impacted*
- ~8,500 employees*
- R&D spend 28% of revenue*

*Full Year 2021

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“Traditional” Clinical Patient Data

- EDC
- Labs
- eCOA
- ePRO
- Randomization
- …

“Traditional” Clinical Patient Data Standardization

The CDISC standard domain models (SDTMIG 3.2)

Special-Purpose Domains:

- Comments (CO)
- Demographics (DM)
- Subject Elements (SE)
- Subject Visits (SV)

Interventions General Observation Class:

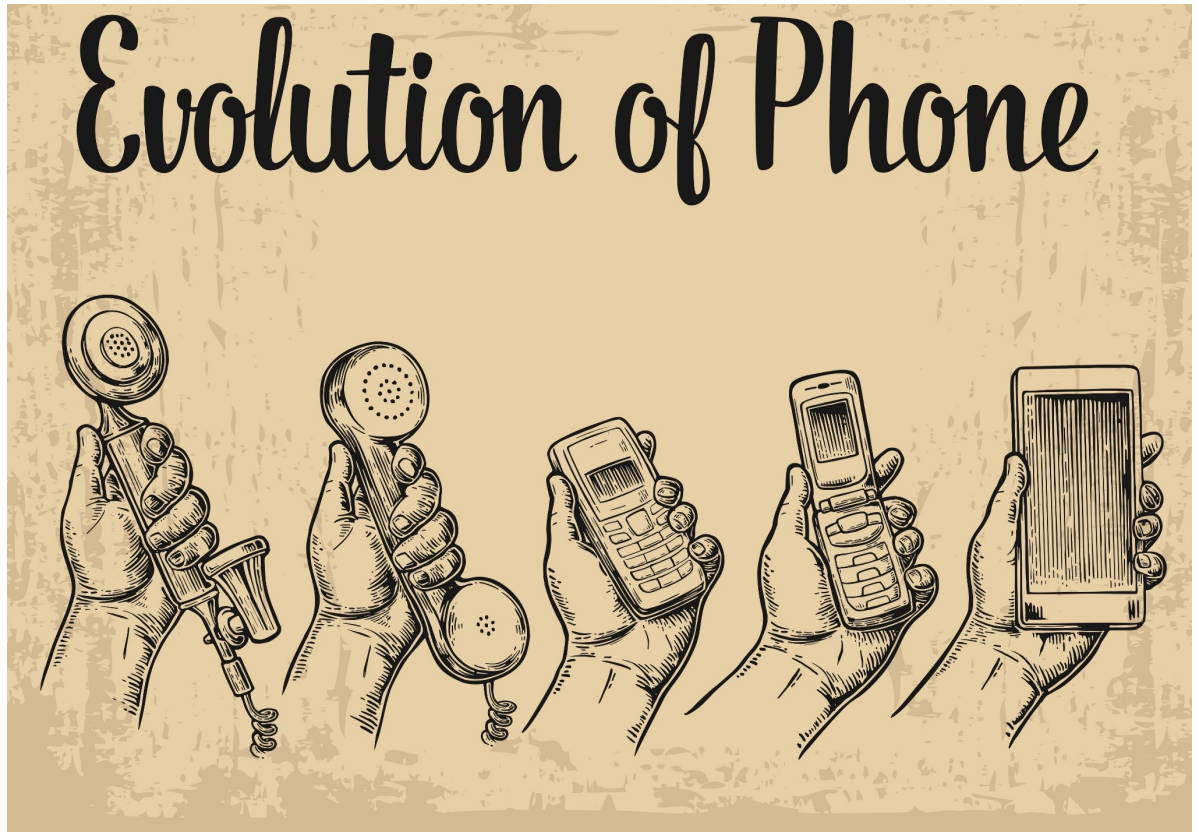
- Concomitant Medications (CM)
- Exposure as Collected (EC)
- Exposure (EX)
- Substance Use (SU)
- Procedures (PR)

Events General Observation Class:

- Adverse Events (AE)

https://en.wikipedia.org/wiki/SDTM

"New" Clinical Patient Data – Innovations



Evolution of Data

- Imaging (beyond MRIs, CAT scans, etc.)
  - In the clinic but also at home
  - Video
- Wearables
  - Vital signs – pulse, blood pressure, respirations, etc.
  - Movement
- BioSampling at home
- Pediatric configurations
- Health care data
- External control arms

Beyond Clinical Patient Data – Operations

What data is available?

- Operations data from the Clinical Trial Management System
- Data for trial feasibility and recruitment
- Submission-readiness data from eTMF systems
- More? There's almost always more

Beyond Clinical Patient Data – Operations

Where is the data located?

- In-house? How many different systems?
- Vendors?
- CROs?

How will you get it?

- Automated transfers?
- Manual or scheduled electronic transfers?
- Hard media?

Clinical Trial Management Systems (CTMS)

- CTMS data includes
  - Trial metadata (e.g., phase, treatments, vendors, etc.)
  - Study milestones (e.g., protocol approval date, first-patient-first-visit dates, etc.)
  - Investigator details (e.g., name, facility, etc.)
- Primary purpose is to track each trial's progress
  - Overall
  - At the country level
  - At the site level
- Additional purposes include
  - Vendor management
  - Identifying trends across trials and taking appropriate action
  - Benchmarking milestone durations across companies
  - Reporting sponsor research engagement to national offices

Clinical Trial Management Systems (CTMS) - Challenges

- Enabling timely, reliable and consistent data across CROs
- Accurate and meaningful reporting
- Ensuring quality data, especially as it relates to 'roll-up' rules across the study, countries and sites

Example

Country	Site	Protocol Approval	First patient – First visit	Last patient – Last visit
1	1	01-Jan-2021	01-Feb-2021	31-Oct-2021
1	2	01-Jan-2021	01-Apr-2021	30-Nov-2021
2	3	01-Jan-2021	01-Jun-2021	<no date>
2	4	01-Jan-2021	01-Aug-2021	01-Feb-2022

When did the first patient visit and last patient visit occur at Site 1?

When did the first patient visit and last patient visit occur in Country 1?

When did the first patient visit and last patient visit occur for the study?

Patient Recruitment

- Timely patient recruitment is critical to meeting the project timelines for a clinical trial
- Companies within the biopharmaceutical industry have been trying to address this for decades
- Active interest in patient diversity is driving new strategies
- Data-driven approaches can be successful but face challenges
  - What data is accessible?
  - What privacy laws need to be considered?
  - How do different national rules affect the process?

Electronic Trial Master File (eTMF)

- An electronic trial master file (eTMF) is a trial master file in electronic (digital content) format. It is a type of content management system for the pharmaceutical industry, providing a formalized means of organizing and storing documents, images, and other digital content for pharmaceutical clinical trials that may be required for compliance with government regulatory agencies. *
- The eTMF is primarily documents, but each item contains a variety of metadata related to classification, signature status, date of provisioning, etc.
- This metadata provides excellent opportunities to
  - Understand progress and trends within a trial, especially when matched against CTMS data
  - Understand trends across indications, studies and CROs
  - Determine progression toward submission-readiness

**https://en.wikipedia.org/wiki/Electronic_trial_master_file*

A Word About Data Science

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Aligning Your A

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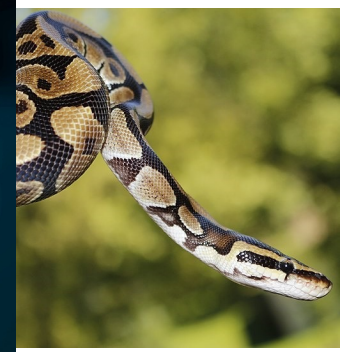

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Opportunities and Obstacles…

- The world of data associated with clinical trials is larger than you might think (Operations)
- It is continuing to expand (Innovations)
- The reporting and visualization of the data tends to get most of the attention from downstream consumers

But, the hard work is wrangling the data so that reports and visualizations are driven by high-quality and timely data

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Any Questions?

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