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Keep clinical trials on track

Avoid these 5 data missteps that create costly delays

During clinical trials, a number of road blocks commonly hinder efficiency, drive up operating costs and put regulatory approval at risk.

Moving a new drug through pre-clinical testing to approval takes an average of **12 years**[1]

85% of clinical trials **experience delays**[2]

1 to 2 of 10,000 drugs that enter pre-clinical trials make it through to becoming licensed treatments

Developing a medicine that gains regulatory approval costs drugmakers **$2.2 billion** double the amount calculated in 2010[3]

Road block 1: Trapped by the trickle effect

Quality of metadata is poor due to content complexity

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Poor data quality triggers manual classification and validation processes

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Manual processes create delays in analysis and report writing

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Delays lead to lags in application filing and regulatory approval

Road block 2: Data wrangling

Instead of focusing on analysis, data scientists report up to **80%** of their time is spent **"data wrangling"**[5]

- ✓ Collecting data
- ✓ Labeling data
- ✓ Cleaning data
- ✓ Organizing data

Road block 3: Clinical trials documentation

Clinical trials produce massive volumes of documentation, particularly in late-stage phases.

Phase III clinical trials generate an average of **3.6 million data points**
3X the amount collected by late-stage trials a decade ago[1]

The volume of clinical trial documents captured is doubling every **18-24 months**

80% of healthcare content is unstructured, changing from one study to the next[7]

Road block 4: There are many, many sources and formats of data

Sources:
Researchers, manufacturers, external labs, patients, healthcare professionals, clinical research sites such as hospitals, clinical research organizations, supply-chain logistics partners

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Data formats:
Clinical trial documents, online forms, IoT data from sensors and devices, paper-based submissions, ePRO/eCOA, EDC, CTMS, IVR, images, labs

Resulting in:

- **Tedious** data collecting
- **Time consuming** data classification
- **Diminished** value of data

Road block 5: Human error

High human-touch methodologies are still widely used to classify and verify trial documents.

50% of clinical trials rely on paper-based case report forms (CRFs) to manage information

This leads to delays caused by:

- Tracking and reporting paper documents[7] **71%**
- Misfiled or missing documents[7] **57%**
- Manual document exchange[7] **48%**

Bring Data Intelligence to Clinical Trials.

Learn how

opentext.com

1 ScienceDirect, "Drugs, Devices and the FDA Part 1: An Overview of Approval Processes for Drugs," April, 2016 2 Accenture, "Decentralize Clinical Trials to Unlock Value for Patients," August, 2021
3 Deloitte Insights, "Intelligent drug discovery powered by AI," November, 2019 4 Medical Sciences Tools, "Drug Development Process," January, 2021 5 Digital Bulletin, "The Problem with Artificial Intelligence in Life Sciences," May, 2019 6 Forbes, "Why Are We Still Waiting Years For Medical Breakthroughs?," May, 2019 7 Forbes, "Why Are We Still Waiting Years For Medical Breakthroughs?," May, 2019 8 Forbes, "Why Unstructured Data Holds the Key to Intelligent Healthcare Systems," March, 2019 9 Sun Global, "Why are We Still Waiting Years Today?" October, 2019 10 Clinical Research News, 12/05/18 Creative Insights Report for Remote Monitoring in Clinical Trials," May, 2020 11 Clinical Research News, 12/05/18 12 Creative Insights Report for Remote Monitoring in Clinical Trials," May, 2020 13 Clinical Research News, 12/05/18 Creative Insights Report for Remote Monitoring in Clinical Trials," May, 2020

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