SUVODA

Unanticipated Change in Clinical Trials:
3 Elements of Complexity

1 Protocol complexity

Amendments and mid-study changes are common

At least 1 substantial amendment

59% of **phase 1** studies[1]

78% of **phase 2** studies[1]

69% of **phase 3** studies[1]

Multiple treatment arms

4x growth

of multi-arm, multi-stage trials from 2019-2020[2]

Personalized medicine

25%

of FDA drug approvals were for personalized medicines in 2019[3]

(up from 5% in 2005)

2 Operational complexity

Increasing drug discovery and development timelines

15-20%

biologics use in clinical trials in 2022

A significant jump from 2010 when biologics comprised 10-15% of all clinical trials[4]

Phase 3 clinical trial duration has grown

1 year longer

From about 2.25 years in 2010 to 3.25 years in 2021[5]

3 Geopolitical complexity

Global uncertainty creates complexity for clinical trials

79%

of studies were affected by COVID-19 in 2020[6]

250+

studies were running in Ukraine as of May 2022[7]

Trial integrity, data integrity, and patient access to treatment in jeopardy due to war.

1 "No End in Sight for Trial Complexity, CSDD Report Reveals", James Miessler, CenterWatch, 2022.
2 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8915371/
3 https://www.ajmc.com/view/number-of-personalized-medicines-doubled-in-4-years-new-report-says
4 "Clinical Trial Duration Trends & The Study Closeout Gap", Justin Culbertson, Clinical Leader, 2022.
5 "Global Trends in R&D 2022", IQVIA, 2022.
6 "The Impact of COVID-19 on Clinical Research in the Life Sciences Industry: Is there a Silver Lining?", Maynard Nexsen, 2021.
7 "The War Puts Ukraine's Clinical Trials—and Patients—in Jeopardy", WIRED, 2022.