SCDM India
Single Day Event

THEME
CDM — Revisiting fundamentals in an evolving clinical research landscape

August 26, 2023, Mumbai
Chandrayaan-3’s ‘failure-based design’ is key to its Moon landing

ISRO Chief S Somanath had said that Chandrayaan-2’s lander’s five engines produced more thrust than expected that led to a bunch of errors. The craft then sped up to correct its course. Moreover, the specific 500x500 sq mt area where it was supposed to land was a very small region. The spacecraft’s ability to turn got limited and the landing became a high-velocity one.

What are the study design considerations in an ecosystem of increased variety, volume, and velocity of data
What is the starting point of CDM involvement in clinical studies and what are key failure modes in the way we approach study initiation and conduct?
What are good CDM approaches for study designs that are patient centric?

- Double-dummy
  - Investigational drug group
  - Active control group

- Crossover
  - Randomization Point

- Randomized withdrawal design

- Factorial
  - Treatment I
    - Dose a
    - Dose c
  - Treatment I
    - Dose d

- Adaptive randomization methods (play the winner, drop the loser designs)

- Randomization by body halves or paired organs (Split Body)