

Clinical Data Management: The Fifth Deflection Point

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Abstract: *At this moment in time, Clinical Research and Clinical Trials are undergoing a massive overhaul and transformation, and the areas that are most exciting are driven by transformation in Process, Platform, Technology and Digital Consulting. Every Pharmaceutical company, no matter how small, now must manage a truly enormous amount of clinical data with all its subjects, sites, studies, standards, etc. The shift of balance is more towards patient value and core research and not so much on clinical trial operations. Over the last two decades, there have been five major deflection points in Clinical Research, let us take a sneak peek at the Deflection to understand its evolution even as we turn back and look forward to the fifth wave of Clinical Data Management where this area has evolved from a traditional, conformed operations program into a transformed, revolutionary data science. In this article we look at five deflection points over a decade from emergence of EDC, beyond EDC, Digital Transformation, Covid Times and Now. The best is yet to come, even as we look forward to more adoption of decentralized trials, scalable integrated, unified data ecosystem, more real-world data, site less trials, virtual trials, incorporation of artificial intelligence; data managers transitioning into a data science role – the 5th deflection point is exciting driven by digital transformation, driven by strategy, driven by passion. The fifth deflection point is Now, and it is here to stay.*

Keywords: Deflection Point, Clinical Data Management, Emergence of Electronic Data Capture, Looking Beyond Electronic Data Capture, Digital Transformation, Covid Times, Unification of Platforms, Advanced Standards

At this moment in time, Clinical Research and Clinical Trials are undergoing a massive overhaul and transformation, and the areas that are most exciting are driven by transformation in Process, Platform, Technology and Digital Consulting. Every Pharmaceutical company, no matter how small, now must manage a truly enormous amount of clinical data with all its subjects, sites, studies, standards, etc. The shift of balance is more towards patient value and core research and not so much on clinical trial operations. Over the last two decades, there have been five major deflection points in Clinical Research, let us take a sneak peek at the Deflection to understand its evolution even as we turn back and look forward to the fifth wave of Clinical Data Management where this area has evolved from a traditional, conformed operations program into a transformed, revolutionary data science.

The first Deflection Point: Emergence of Electronic Data Capture

The first Deflection point was in the early 2000's when clinical trials were paper based, during this era, management of trials was an arduous process with a paper-based mechanism involving scanning of handwritten CRFs, imaging, indexing, double data entry with cumbersome batch validation, query generation required faxing/ mailing of Data Clarification Forms with cycle time of a week to 10 days with a possibility of response getting lost in transition. Then came Remote Data Capture which was quickly replaced with emergence of Electronic Data Capture with introduction of new platform providers in this space.

The Second Deflection Point: Looking Beyond Electronic Data Capture

In the late 2000s mandate was to go beyond just EDC, it was a leap to bring in "business transformation" and the buzz word was "electronic" (eSubmission, eDiary, etc.). The voice from Pharma was loud and clear to bring in standardization, introducing Data Life cycle Packages, Standards were established resulting in ODM (Operational Data Model) that became a gold standard for storage,

interchange between data management systems, study metadata, Integration of EDC with other clinical applications. This era also saw the rise of open-source EDC software, independent standards for characterizing and sharing data (like CDISC).

The Third Deflection Point: Digital Transformation

The key industry driver in the early 2010 was pressure due to global recession on top line and bottom line with drought in capital investment, to reduce cost of ownership by pharma and increase operational efficiency. This era can be rightly called the start of Digital transformation with service providers adopting ways to be nimble and agile. It was a call to address changing needs while leveraging innovative technology with key focus on Cloud hosted end to end model. There was an emergence of Service providers and CROs venturing into BPaaS (Business Process as a Service) and PaaS (Platform as a Service) model providing a combination of platforms and services, Real-time data interchange for efficiency and timely decision making based on data collation through different source systems, social media became a source of health-related information; Remote Monitoring to an extent played a pivotal role in monitoring visit frequency. There was an adoption of Real-World Data and Real-World Evidence.

The Fourth Deflection Point: Covid Times

This era can best be described by saying "technology made the world smaller", Clinical Data Management saw a paradigm shift from conventional methods of delivery into a new age business model where Technology played a pivotal role in the conduct of clinical trials, ranging from EDC to CTMS, from randomization to IVRS/IWRS, safety gateway, web services, agility in vendor data management, emergence of mobility and other device based solution that is was adopted at various stages. This enhanced and fastened data review and decision making. Covid also brought in acceleration in drug approval time frame getting more robust and broader avenues for data to be managed and analyzed across sites, countries and continents.

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The Fifth Deflection Point: Our Times and Beyond

If one Industrial revolution and two world wars resulted in a new world order, Clinical Data Management similarly has had a significant shift in the way Clinical Data Management transformed into Clinical Data Science Post Covid.

Smarter data management with a shift from conventional project-based solution to a digital-data and process driven-model with laser focus on some industry wide initiatives listed below:

- 1) Conversational Artificial Intelligence /Machine Learning capabilities providing multi layered analytical capabilities to enhance consumer insights, increase process efficiencies. Shift from descriptive to prescriptive, predictive models. Using AI-ML for management and validation of data pertaining wearables, biomarkers, biosensors, etc.
- 2) Unification of Platforms – Integrated, Connected Model with seamless navigation with an interactive responsive UIbased output platform
- 3) Advanced Standards Adoption: Leading Pharma and TransCelerate initiatives in data standardization have led to adoption of advanced standards not just in clinical data management but also SDTM, E-source across functions e.g., data captured in EMR or processed as HER and Data exchange through XML –EDC modelling using ODM
- 4) Trial data collection using ePRO, eConsent, Smart devices (wearables), eScreening, eCOA, Direct EMR, eHR, data capture, real world evidence with a built-in ability to harness the power of an integrated analytics and business intelligence
- 5) Shift towards Patients with focus
 - Patient Centricity – shift towards providing Patient Experience
 - Remote Consulting, Telemedicine, Smart Questionnaire
 - Virtual Site Training, Decentralized Trials
 - Trial Disclosure to patients
- 6) Trial data collection using ePRO, eConsent, Smart devices (wearables), eScreening, eCOA, Direct EMR, eHR, data capture, real world evidence with a built-in ability to harness the power of an integrated analytics and business intelligence

The best is yet to come, even as we look forward to more adoption of decentralized trials, scalable integrated, unified data ecosystem, more real-world data, site less trials, virtual trials, incorporation of artificial intelligence; data managers transitioning into a data science role – the 5th deflection point is exciting driven by digital transformation, driven by strategy, driven by passion. The fifth deflection point is Now, and it is here to stay.