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The implementation of the evolving Clinical Data Science role, a cross collaborative initiative

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One of the most recent topics in the industry is the introduction of data science to clinical trial strategy, execution and evaluation. Although adoption approaches differ based on individual companies' data strategy, the reasons for the drive behind the change is clear, and these include:

- Data sources which have become more and more diverse. In the past clinical trials were very linear in data collection and mainly centralized around the EDC (Electronic Data collection) platform. Today there are multiple different data sources (most of these hosting eSource data) holding the same if not more data than the EDC platform
- The way data is now being collected through wearables and other eCOA driven methods, as well as huge laboratory datasets such as genomic datasets, produced more data points than we have ever seen before
- The ability to collate all data sources in order to make insightful and timely decisions is not only a necessity to ensuring patient safety but also a cost saver in ensuring decisions are being made at the right time. This drives the need to have data flowing into a collated space and much higher frequencies than we have managed in the past
- Recent regulation updates (specifically ICH E8 and ICH E6) which call for data surveillance and a risk strategy inclusive of data orientated risks
- The release of ML and AI tools to not just expedite processes but also allow for much higher volumes of data processing. This is already common practice in many other industries and there is an external pressure to ensure we are using this technology to ensure the progression of the pharmaceutical industry too
- Then lastly, there has been a realization in the industry that the data collected from the clinical trials should be seen as an asset to be mined and evaluated for insights to support future trials. This not only mitigates risks for future studies but also can help in the strategic planning of those trials.

From the above requirements, tools and/or technologies are required to facilitate these requirements. There are of course many technologies available with a range of abilities, however at minimum a company's' strategy should include a data collation environment (eg: A CDR/MDR or enterprise data lake or something similar) and an analytics (preferably including visualizations) platform connected to the collated and ingested data.

The specific focus area for a company is dependent on several variables such as Therapeutic area (and/or focus indication), general trial designs, company size, historical areas of focus, etc... and this additionally seems to be driving in which group (or groups) within a company that is driving the change.

Although this requires a holistic study team approach, the need for additional insights into the data is a major driver.

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