

11. Conclusions

Ultimately, CDM must ensure the veracity of data coming from a variety of sources with high volume and high velocity. Technology must allow Clinical Data Scientists, supported by Virtual Clinical Data Managers, to ultimately extract the full value of clinical research and health care data as illustrated by figure 7 below.

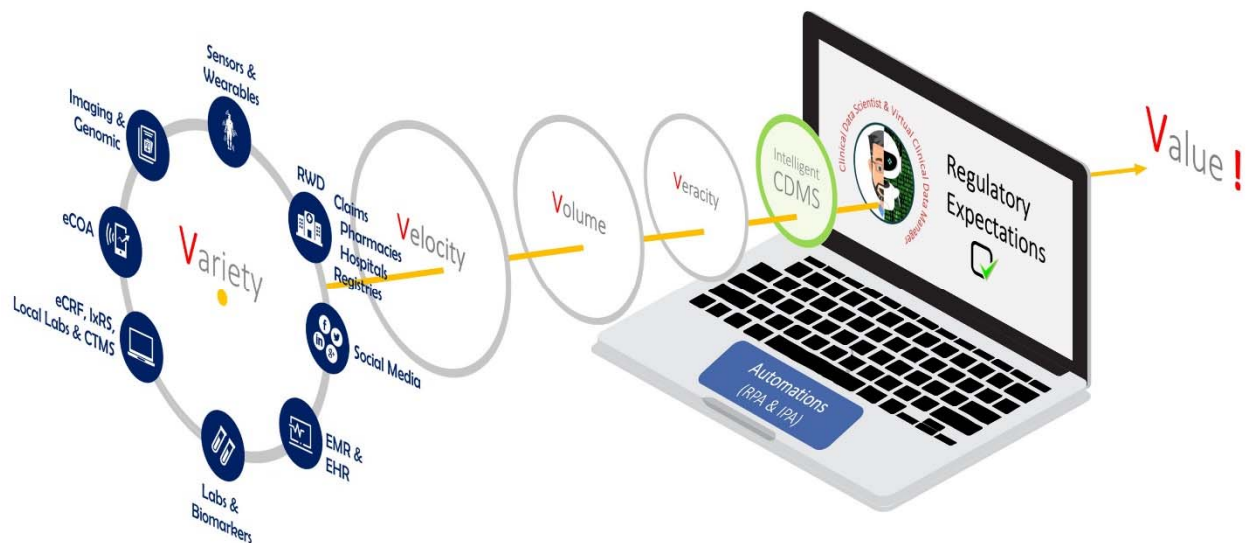


Fig 7. The 5Vs data journey from collection to value generation

In such a context, technology must become the enabler to a true and scalable change allowing CDM to meet the demand of clinical research while remaining compliant to increasing regulatory requirements.

CDM needs to leverage technology to:

- Unleash the data potential by generating valuable insights from raw data
- Find the needle in the haystack to identify data issues threatening data interpretability with advanced capabilities such as ML and AI
- Use automated and metadata-driven solutions for data aggregation and transformations
- Use RPA and IPA solutions to automate simple and repetitive tasks
- Leverage direct data capture and be DCT-proof (true e-Source, means no SDV and no queries)
- Be ready to support non-traditional protocol design (e.g., Master Protocol, Adaptive, etc.)
- Integrate and unify data coming from a growing number of systems to intelligent CDMS
- Ease inspections

In conclusion, technology is the key enabler of our evolution to CDS. CDM organizations should consider the elements outlined in this paper, as well in those in the first SCDM reflection paper (Part 1), to set their organization's vision and its corresponding roadmap to success.