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Alcon and Illumina: Unifying EDC to Address Protocols and Various Data Sources

The medtech industry is rapidly transitioning to a digital clinical infrastructure to address evolving regulations and inefficiencies with manual processes and data management systems. Alcon and Illumina are two medtech organizations that realized the value of transitioning to a digital approach.

During a panel discussion at Veeva MedTech Summit, Leianne Ebert, head of global data operations at Alcon, and Phil Tayco, associate director, clinical data management at Illumina, shared insights on the challenges, implementation best practices, and outcomes of their respective transformations, including:

- Unifying clinical data management to reduce manual effort
- Ensuring analysis-ready data at all times
- Driving faster study builds

In addition to investing in modern technology, process improvement, a strong partnership, and training were essential to realizing their vision.

Laying the foundation for a digital clinical infrastructure

In order to effectively implement a digital clinical infrastructure, Alcon and Illumina emphasized the value of a phased approach to implementing the Veeva MedTech Vault Clinical Platform and extensive training processes. Ebert and Tayco both cited managing CROs and internal resources, establishing standards and protocols, and maintaining data integrity across broad data sets as key challenges. Making the transition required an easy-to-implement system and phased approach to reach their objectives.

One of Illumina's first initiatives was to bring their studies in-house and centralize the clinical infrastructure. Tayco stated that they "started with investments in eTMF and CTMS, with the opportunity to bring CDMS into the infrastructure . . . That led to all studies being brought in-house to make the most of the environment." Today, Illumina builds and manages all of their own studies.

Alcon was heavily focused on implementing core solutions quickly in order to speed up their study builds with a longer term plan to implement multiple solutions from the beginning. In an effort to expedite the process, Alcon deployed the end-user interface to build databases in October 2019, and were pushing studies live as early as February 2020. The company now has more than 130 clinical studies in Vault CDMS after making the strategic decision to internalize data operations and train their CROs on the process.

In both instances, establishing an internal governance model and long-term deployment strategy ensured a successful implementation and opportunity for growth.

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> — Phil Tayco, associate director, clinical data management, Illumina

Achieving autonomy through hands-on training

Alcon took a hands-on approach by partnering with Veeva to train their team during initial study builds. “We started by learning from Veeva and their dialogue, while simultaneously training with a mentorship approach for the next two builds” Ebert said. “Then we moved forward with a long-term engagement plan where we were doing practically all of the builds independently.” This approach helped drive adoption and ownership among internal stakeholders at Alcon, while maintaining support from Veeva on more complex builds.

Illumina followed a similar process in terms of training and enablement with a focus on rapid prototyping and agile design. With a lean operation of less than ten people, Tayco emphasized the need for a consistent, reliable, and flexible solution to reduce the burden on his team. As Illumina implemented a digital infrastructure, he noted a shift in their approach: "Previously we gave protocols and wrote specs for CROs to do the builds. Knowing that we were going to bring that in-house, we decided to use the design environment to do the builds, prototype them with our data collection team, and make sure we have the right CRF design in place." By streamlining this process, Illumina was able to reduce dependency on creating custom edit checks in programming and focus more attention on data review, optimization, and transfer logistics.

By leveraging technology and implementing process improvements, Alcon and Illumina were able to more efficiently manage resources and scale study builds.

Implementing standards to maximize trial efficiency at scale

As Alcon and Illumina introduced additional studies and stakeholders to Vault Clinical Platform, implementing standards and taking an iterative approach to the design of future studies became increasingly important to streamline the overall trial process.

Illumina leveraged their refined ecosystem to standardize processes and minimize the burden on their team. Tayco was eager to shorten timelines, stating that "we have a few study types that we deal with, but within those study types you have the same case report form and data elements. That led to an opportunity to utilize our CDMS, CDB, and existing processes to not only meet a timeline, but reduce it. It is all happening automatically within the Vault Platform and that could not have happened without the standardized processes and enablement that occurred prior to that."

Alcon established clear objectives to build their standards and new studies and reduce their data clean cycle from 20 to less than 14 business days. To realize these goals, Ebert stated that "it is important to understand what you are working towards and take it one step at a time. We focused on getting the core foundational layer done . . . what that did is get us to 50% standardization on every single study. At the end of last year, we established therapeutic standards and were able to enhance that number further to 80%, exceeding our goal of 75%."

By taking a phased approach and establishing clear and achievable goals, Alcon and Illumina were able to make a clean transition and achieve faster deployments as they built their digital infrastructure.

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— Leianne Ebert, head of global data operations, Alcon

Four key takeaways for clinical leaders

As you consider implementing a digital clinical infrastructure, consider these four insights from our panelists:

1. **Take a phased approach to implementation**
   A successful transformation requires a long-term plan with a phased approach. Alcon and Illumina prioritized critical applications, versus nice to haves, to support digital transition. Once core components were successfully implemented, both companies had a strong foundation to scale their efforts and introduce additional applications.
2. **Hands-on training to establish autonomy**
   Ensuring that all stakeholders are properly trained and enabled to maximize new systems is critical to long-term success and adoption. Alcon and Illumina established clear training protocols during initial study builds, allowing them to establish process and autonomy over the system as they scaled.
3. **Take an iterative approach to standard and protocol development**
   Maintaining and improving standards and protocols is an ongoing process. By taking an iterative approach, Alcon and Illumina were able to find opportunities to continuously improve their methodology, reduce burden on their teams, and save time.
4. **Define clear KPIs and goals**
   Adopting new technology is as much about process improvements as it is about growth and scale. Alcon and Illumina were diligent in defining KPIs and goals to track their progress and define success as they scaled operations.

The Veeva MedTech Vault Clinical Platform enables our partners to streamline their processes, address protocols, and collect and maintain integrity of inbound clinical trial data – all under a single software solution.

Interested in hearing more from the panelists?

Leianne Ebert: Growing with a Multi-Solution Provider: 4 Years of Improvement at Alcon

Phil Tayco: Managing Multiple Data Sources with Vault CDMS

Learn more about unifying clinical data and operations leveraging the Vault Clinical Platform.