Make DCT land better:

CLOSE GAPS BETWEEN REGULATIONS AND PROCESS

Syneos Health

Objective

1 Identify gaps between the constantly changing regulations about Decentralized Trials and Digital Health Technologies world wide, and Syneos health processes, using Kaizen and lean six sigma methodology , to determine opportunities and solutions that bring Syneos full allignment with regulations and benchmark against the industry to become leaders.

2 Provide competitive advantages considerign market need, improving quality on Syneos studies involving DCT, working on client retention, providing operational efficiencies that ensure patient safety, avoid audit and inspection findings and GDPR penalities.

Methods

Project started in Jul 2022 identifying a core team with DCT managers, Quality management specialized on DCT and a Bussiness process Optimization facilitator, that worked virtually to design, dicuss and create the project, having the following stages:

Phase 1

Close review of the regulations existing at that time, such as the draft guidelines for Digital Health technogies from FDA, the EMA guidance on computarized systems, the MHRA (United Kingdom) and some country guidelines on DCT like Denmark , Switzerland and Sweden, and the review of the company processes related to those topics in bussiness units like Quality, vendor management, Data management, DCT, regulatoiry and strat up, project and risk management, Biostatistics, Information technology, data privacy and impact. Or the involvement in new initiatives discussions like the company creation of data flows.

Phase 2

Review processes with stakeholders and identify the gaps, segmenting a summary matrix in to four high level themes 1, Data management and clinicla endpoints, 2, Validation, 3. Risk data and data integrity and 4. submissions. Then initiate one kaizen event for each area identified, with the key stakeholders form the bussiness units ownling the processes or particiating on them, to then and create a mural board that linked stakeholder to right themes. That process lasted 3 months.

Phase 3

The core Kaizen team performed an analysis of the insights and gaps discussed and created and Opportunities PICK chart identified by theme and type: process change, vendor support, controlled document change, training. Creating four workstreams for each high level themes and discussed with stakeholders to identify solutions, higher esclations needed for the need of new potential roles and processes associated.

New regulations were published or became effective during the process, like the EMA guideline on computarized systems, the recommendation paper on DCT elements also from EMA, the electronic system, records and signatures in clinical investihations by FDA or the DCT guidelines by Taiwan.

Phase 4

Once opportiunites were discussed wiuth the key stakeholders per theme, distinct worksteams agreed with accountable leads, assessed baseline from the improvements required, created action plans for each worksteam, consolidate timelines on deliverable to be achieved, and started to measure impact.

Results

- The Decentralized trial team and the core Kaizen team was able to identify the key stakeholders needed in the discussions to really address the gaps and opportunities identified, makign aareness not just on the regulations existing but on the importance of having communication between bussiness units to link the processess and not having them in silos, which improves efficiences and makes a better risk assessment, which is the pillar of almost all regulations received and analized.
- It was also identified that Syneos health was already in complaince with almost all requirements from the regulations, needing only to re check the process to allow DCT elements to be involved or added into the existing process, or having recently created roles like the Data scientist team, been added on early stages of the protocol, that involves pre award, to early identify potentual trisks related to data handlign when using DCT components, as this role is focused on identifying and address data risks from they clinical and data management experience and perspective.
- Syneos has a current process of controlled document review that involves leads from each bussiness unit, in constant coimmunication with all other units as to have crossfunctional review of the processes with ongoing periodicity. That is promiting the continuous improvement.
- The area with more challenges and opportunities identified was validation, as even if the company has validation managers and processes in place, they mainly focused on internal systems, but with this analysis the company is seeing how efficiencies can be applied to have this knowledge passed to other study areas like the use of DCT and any other Digital Health technology , specially after the guidance from EMA on computrized systems.
- On this particular theme are of validation, Synoes was able to identify that two levels of validation are currently needed, one at Core or comàny level, specially for contarcted vendors who are providing Digital Heath solutions for clinical studies, for which Synoes has an strong process or qualification athat involves audits by specialized team on the field, but opportunities of improvement were identified as to make the process faster and more robust, to ensure the processes and way to work from our qualified vendors are aligned with the regulations and syneos processes.
- The other level of validation is at study level, and needs to be assessed case by case , considering the technoligy added to each project, having a focus on risk assessment and validation fo the digital health technologies added, and that is the current focus of the company now to ensure the correct documentation for validation is not created and or requested to vednors, but also filed intro Trial Master file and socialized with internal and external stakeholders as applicable.

Conclusion

- The Decentralized trial team and the core Kaizen team was able to identify the key stakeholders needed in the discussions to really address the gaps and opportunities identified, makign awareness not just on the regulations existing but on the importance of working together to gain efficiencies.
- Syneos Health has a department of Decentralized trials with dedicated Subject Matter Experts that are able to work crossfunctonally and worldwide, provide input to other bussiness units processess and participate in productive risk assessment discussions, which is the pillar to most of the regulations published to date.
- Syneos Health upper management is committed with the use of innovation and new technologies, but with the needed control to ensure patients safety and regualtory complaince, and that is why it is very important for the company to keep high quality of their processes having a process to contiunuously improve processes, which is makign the implementation of regulatory requirmenmts easier and quicker.
- Syneos Health invest in the importance of having good validation support at core level and study level, studying the possibilty to create new roles or improve the skills of existing ones, to allow this to happen for trials that will deliver quaility data, that support new approvals which bacome new medications that improve patients health and quality of life.