W-12

The Clinical Development Design (CDD) Framework: Assisting and Improving Decision-Making for Product Development

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Abstract

Track/Interest Area: Data Standards – Clinical Trial Design
Keyword: Design Decisions, Product Development, Design Stakeholders, Information Model, REDCap, Cmaps
Objective: To explore structured criteria using design principles and the tracking of decisions during medical product development programs in order to achieve an understanding of the impact of the major factors affecting decision-making and the improvement in such decision-making in future.
Methods: We identified product development key decision points and extracted terms to establish a Clinical Development Design (CDD) Framework ontology. This Information Model integrates decision points with data from 3 databases, eCTD, Risk Review, and Design Structure, to make generic concept maps (Cmaps).
Results: The generic Cmaps provide a framework to capture, modify, and link the key process flow and decision elements for the clinical development of a medical product from inception to post marketing surveillance. The interactions at each step, the drivers, and the manifestations of changing input, decision results, and downstream effects can be viewed retrospectively, modeled prospectively, and used to analyze projects on a comparable basis, independent of product type or therapeutic area. Through the ontology-based Cmaps, resource planning and quality assurance can gain greater precision and reproducibility. Regulatory strategy, knowledge gaps, and other options can be identified and optimized while accounting for relevant factors.
Conclusion: The CDD Framework, ontology, and Cmaps offer stakeholders in clinical research an opportunity to view the decisions made from the original clinical research question to post-marketing surveillance and the impact of various factors on decision, data, and business outcomes. The Cmaps are part of a learning system that can accommodate new methods, guidance documents, formats, concepts, and terms through the structure of the CDD ontology and integrate information from linked databases. The Cmaps allow identification and tracking of the key enabling information that supports or leads to specific decisions and outcomes.

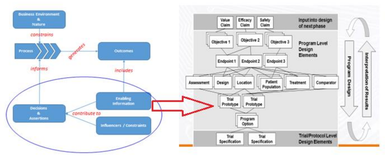
Methods

1 - We have collected our terminology in REDCap[1] using descriptors from the FDA Target Product Profile (TPP), the eCTD specifications, ClinicalTrials.gov, AstraZeneca's Design to Deliver, CDISC Glossary, ICH E6, and other clinical research resources. We entered the data into our CDD Ontology database recording the term, description of the term, references, and keywords.

2- For the Information Model delineation we are using the IHMC Cmap tool[2] that allows us to show the linkages and relationships between the terms. We began with a generic version of what needs to be in a CDD Framework (CDDF) Cmap. Using the generic version of the CDDF Cmap, we applied the structure to the Efficacy Claim and the Risk-Benefit Profile.

Figure 1 describes our starting place.

Fig. 1 Proposed Clinical Development Design Information Model



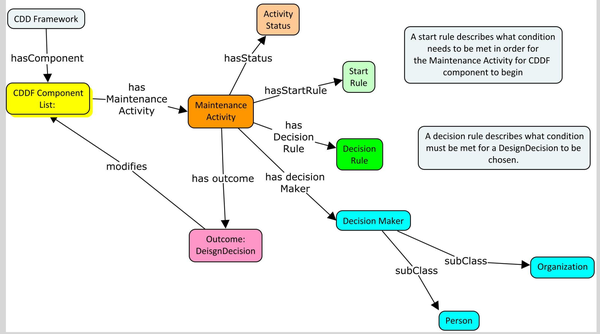
Questions:

- *How do you see structuring design decision-making benefitting your drug development processes?*
- *What is the key information that we need to capture around design decisions?*
- *What would you like to see added to this model?*

Results

Figure 2 is a generic Cmap that we are using as the base for all of our development work. Using our previous work on SMART Design[3,4] we began by building a prototype of what belongs in a CDD Framework Cmap. The Cmap makes it easy to move the concepts and linkages around until we produce a viable and sensible mapping of the information. Cmaps allow you to show how the linkages and concepts are related.

Figure 2. Generic Clinical Development Design Framework



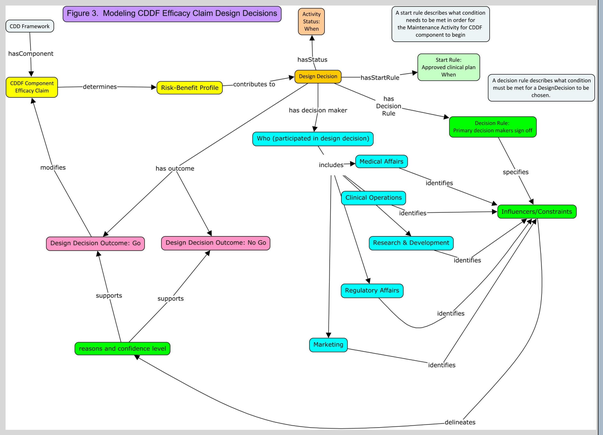
Questions for Figure 2:

- *What do you believe are the essential components for the CDD Framework?*
- *How would you define a decision maker?*
- *How would you define a Design Decision?*

Applying Figure 2 to Figure 3, we are using an Efficacy Claim with a Risk/Benefit Profile that is maintained by a set of design decisions. The Design Decision is our Maintenance Activity on this map. The Activity status tells us when the project started and where we are currently. The Start Rule tells us when we have started and why we started – there is an approved clinical plan. The Decision Rule tells us what the Decisions Makers signed off and then links to why they signed off.

In addition to capturing design rationale as free text, we can track specific criteria linked to design decisions as enablers / blockers, or influencers / constraints. Best practice can be evolved by understanding what decision making criteria teams have applied, and how they rationalized / optimized their decision.

Figure 3. Modeling CDDF Efficacy Claim Design Decisions



Questions for Figure 3:

- *Do you have an example that can be applied to Figure 3?*
- *How would your picture of design decisions differ?*
- *In what detail should we be capturing design decisions?*
- *How do you think that we should capture the rationalizations for design decisions?*

Conclusion

Linking, relationships, and the ability to search and map how design decisions are made form the basis for our work. In this presentation, we have asked a number of questions from you, our stakeholders. With your input we are looking forward to improving the design framework.

References

1.Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. Journal of Biomedical Informatics 2009;42:377-81.

2.IHMC. Cmap Concept Maps. 2014. (Accessed June 18, 2016, at http://cmap.ihmc.us/.)

3.Vasko L, Sundgren M, Bachmann P, et al. Smart Program Design Through a Common Information Model. Therapeutic Innovation & Regulatory Science 2014;49:116-25.

4.Banach M, Ko H-S, Hirschfeld S, et al. Barriers and Solutions to Smart Clinical Program Designs. Appl Clin Trials 2018;27:10-7.

Disclosure

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