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Standardization Efforts at Medtronic, Benefits and Lessons Learned

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ABSTRACT

A standard data model is defined as a data model that is widely applied in some industry and shared amongst competitors per Wikipedia. Data Standards in our industry can be defined as a framework including structures, vocabularies, and business processes that enables the efficient conduct of a clinical trial. In the context of this paper, standardization refers to creation and build of standard CRF's, database per CDISC standards up until the creation of SDTM Datasets.

Standardization helps organizations by increasing efficiency, quality, generates savings and eventually helps us submit our data in compliance with regulatory agencies requirements such as US FDA. It is becoming commonplace that regulatory agencies in United States, Europe, and Japan are requiring organizations to submit their data in a CDISC compliant format. This is especially true for Pharmaceutical industries and similar requests are expected to reach medical device industry soon. Medtronic has proactively adopted CDISC standards to reap the aforementioned benefits. This paper aims to glance at the standardization efforts that were adopted by Medtronic across various business units, benefits of standardization and the lessons learned during this process in a case study format.

INTRODUCTION

Medtronic is a global healthcare solutions company committed to improving the lives of people through their medical technologies, services, and solutions. Medtronic has six main business units with several smaller business units operating under them. Adoption of CDISC standards across Medtronic is a huge challenge considering the size of the organization, therefore Medtronic took the approach of optimizing the case report forms to meet the end goal of standardization and this paper provides a peek at this process.

THE CHALLENGE AND THE SOLUTION

Some of the challenges faced by Medtronic are:

- The scale and the size of the Organization.
    - Implementing standards across multiple business units.
    - Looking at the process holistically so business units are not working in silos.
- The cost associated with incorporating standards.
    - Dealing with the fear of the unknown as standards are new to Medtronic.
- Educating the organization on long term benefits with adoption of the standards.

THE TWO-FOLD SOLUTION

The solution that is adopted is two-fold:

- Optimization of Case Report Forms: a unique approach to creation of case report forms which are standard.
- Data Standards Review Process: an approach adopted at Medtronic to sustain the standardization efforts.

OPTIMIZATION OF CASE REPORT FORMS

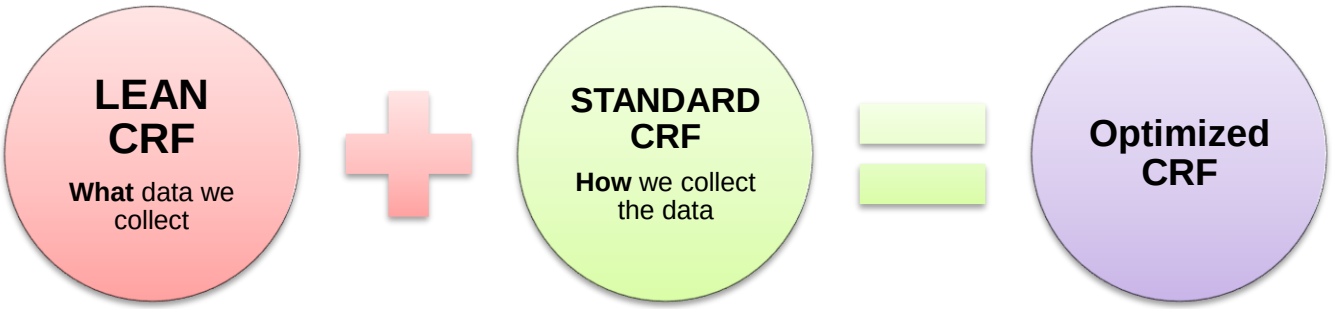

Figure 1. Build of Optimized CRF

Optimization of Case Report Forms consists of two steps, leaning Case Report Forms and standardizing Case Report Forms. Leaning of Case Report Forms entails collecting only data points that are important and pertinent to the study. Next step is to standardize what we collect, during this step how we collect the data is defined by following CDISC standards so the questions/forms being collected are CDISC compliant. The output is an optimized case report form which is not only CDISC compliant but also Lean.

The next step is to optimize the Case Report Forms across Business Units. To achieve this, Optimization is performed by reviewing case report forms that are collected in a similar manner across studies irrespective of Business Units. These are forms such as Demographics, Adverse Event, Medical History, Device Events etc. and are called “Enterprise” Case Report Forms and will be represented as “Enterprise Case Report Forms” hereafter in the paper.

Now that the basic set of case report forms are optimized, the same approach is applied for Business Unit specific case report forms and these are called “Therapeutic Area Standards” and will be represented as “Therapeutic Area case report forms” hereafter in the paper. To build a new study, the study Case Report Forms will be a mix of questions from Enterprise case report forms, questions from therapeutic area case report forms plus any study specific questions that are unique to that given study.

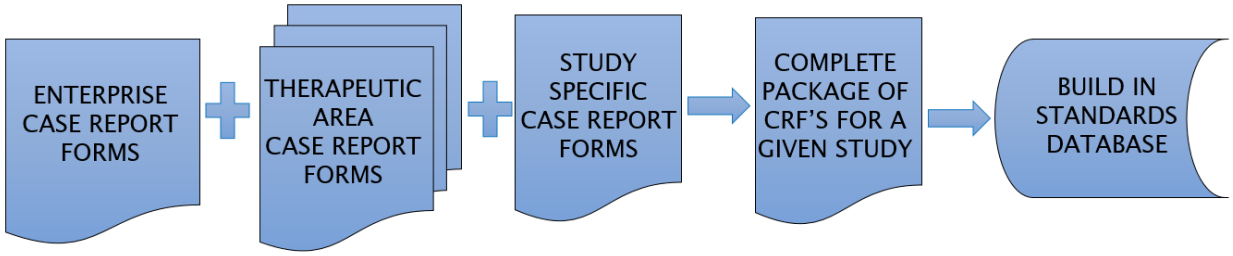

Figure 2. Build of Case Report Forms in Standards Database

A global library is maintained by the global librarian which acts as a repository for all the questions that are being built per standards so that when a new study is being build the standard questions can be re-used, a corresponding standards Electronic Data Capture database is also maintained which can be leveraged to start the build of a new study.

SDTM conformance is performed on studies that are build in the standards database so that when a new study is being conformed to SDTM then that study can leverage SDTM datasets that are common across Business Units such as AE, MH or DE. Since the SDTM datasets can be re-used for every study this saves a lot of time when creating SDTM datasets for a new study. A new study would only add mappings for study specific questions when creating SDTM datasets as all the other questions are already conformed for Enterprise and therapeutic area case report forms. This results in end to end standardization that we are aiming for, to standardize case report forms, database and SDTM datasets.

DATA STANDARDS REVIEW PROCESS

To sustain the efforts that we put forth in the Case Report Forms optimization, a standards governance process called the Data Standards Review Process is put in place. The goals of the Data Standards Review Process are to:

- Review request of a new study's case report forms which entails a stringent process to oversee the leaning of Case Report Forms and to promote adoption of standards.
- Check that consistent adoption of standards is occurring across new studies.
- Provide guidance on data collection, development in Electronic Data Capture (EDC) environment.
- If SDTM datasets are requested, SDTM datasets are generated as well.

Every new study must go through the Data Standards Review Process unless exempt so the standardization efforts are sustained.

BENEFITS AND LESSONS LEARNED

Next section will cover benefits and lessons learned at Medtronic.

BENEFITS OF MEDTRONIC'S INVESTMENT IN CDISC STANDARDS

Some of the benefits that Medtronic is able to reap due to investing in standards are:

Efficiency:

- Faster creation of CRFs
- Faster creation of EDC (Electronic Data Capture) views and variables
- Faster creation of SDTM datasets
- Faster reporting for data review and data analysis
- Acceleration of study timeline

Quality:

- Maintain a high level of quality
- Consistent data collection within Medtronic and for customers
- Consistent SDTM mappings across studies
- Easier to update standards such as Controlled Terminology (quarterly updates), SDTM Model updates (easier to update newly added variables at SDTM Model upgrades).

Savings:

- Re-use of standard CRFs
- Re-use of standard SDTM mapping
- Reduction in study Cost
- Utilization of one database

Regulatory Compliance:

- Agencies in US, Europe, and Japan are stating they will require submissions in a CDISC format in the near future for Medical Device Organizations. Adoption of standards upfront gives Medtronic an added advantage
- Global Regulatory Compliance
- Accurate and timely submission and responses to Regulatory agencies

LESSONS LEARNED

Some of the lessons that we learned along the way are:

- We didn't anticipate such great early adoption across different business units, we didn't have enough trained resources (resources that are trained on CDISC standards) to take on the large amount of work coming our way via Data Standards Review Process.
- In order to meet the high demand, there was a need for more upgraded tools to perform the Data Standards Review.

CONCLUSION

In conclusion, the results that are achieved as a result of standardization efforts are:

- All the Therapeutic area case report forms have now been optimized and SDTM datasets have been created and are ready for use. Any new study that will go through the Data Standards Review process can leverage these.
- Thirty plus studies have now been built in the new standards database utilizing the Data Standards Review Process.
- We noticed an early and proactive adoption of standards by different business units.
- The pilot study that went through the Data Standards Review Process reused eleven of the thirteen Case Report Forms of the study which just goes on to show the extent of proactive adoption by business units.

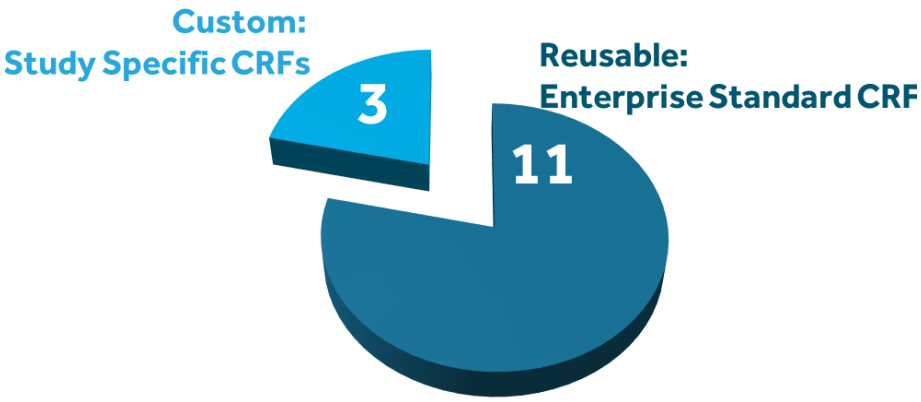

Figure 3. Results from Pilot Study's Data Standards Review Process

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