

The development of standards management using EntimICE-AZ

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INTRODUCTION Historically, using excel has been the main system for organizing and storing metadata, within AstraZeneca and the wider industry. Excel is particularly challenging when it comes to managing versions, reuse of the standards and sharing with vendors. This paper, will share how AstraZeneca is planning to change the standards governance using the implementations of EntimICE-AZ system developed by entimo. Early Clinical Development (ECD) within AstraZeneca, which specialises Phase I and II trials it is important to have easy access to the latest controlled standards to swiftly implement those in the dynamic study execution phase

ECD BENEFITS Central organisation developing the corporate core standard, Sharing standards cross science units for swift access to standard references during standards enhancement, One source of generic core standard for all AZ studies regardless of phase, Simple request system within the system for quick standards augmentation, Dedicated ECD area for specific early phase standards, Support submission process once a project is handed over for late phase development when standards is used cross science units

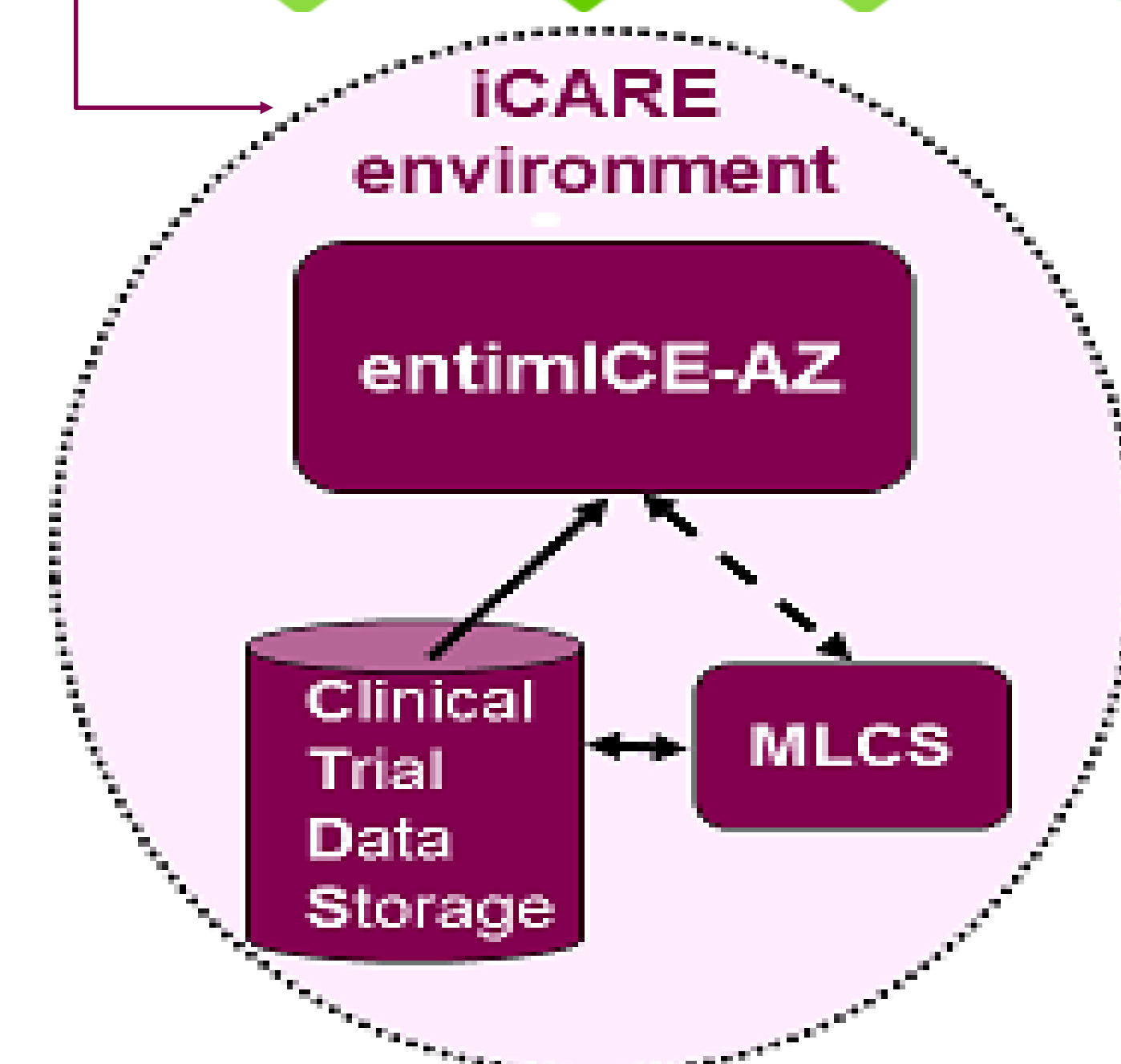
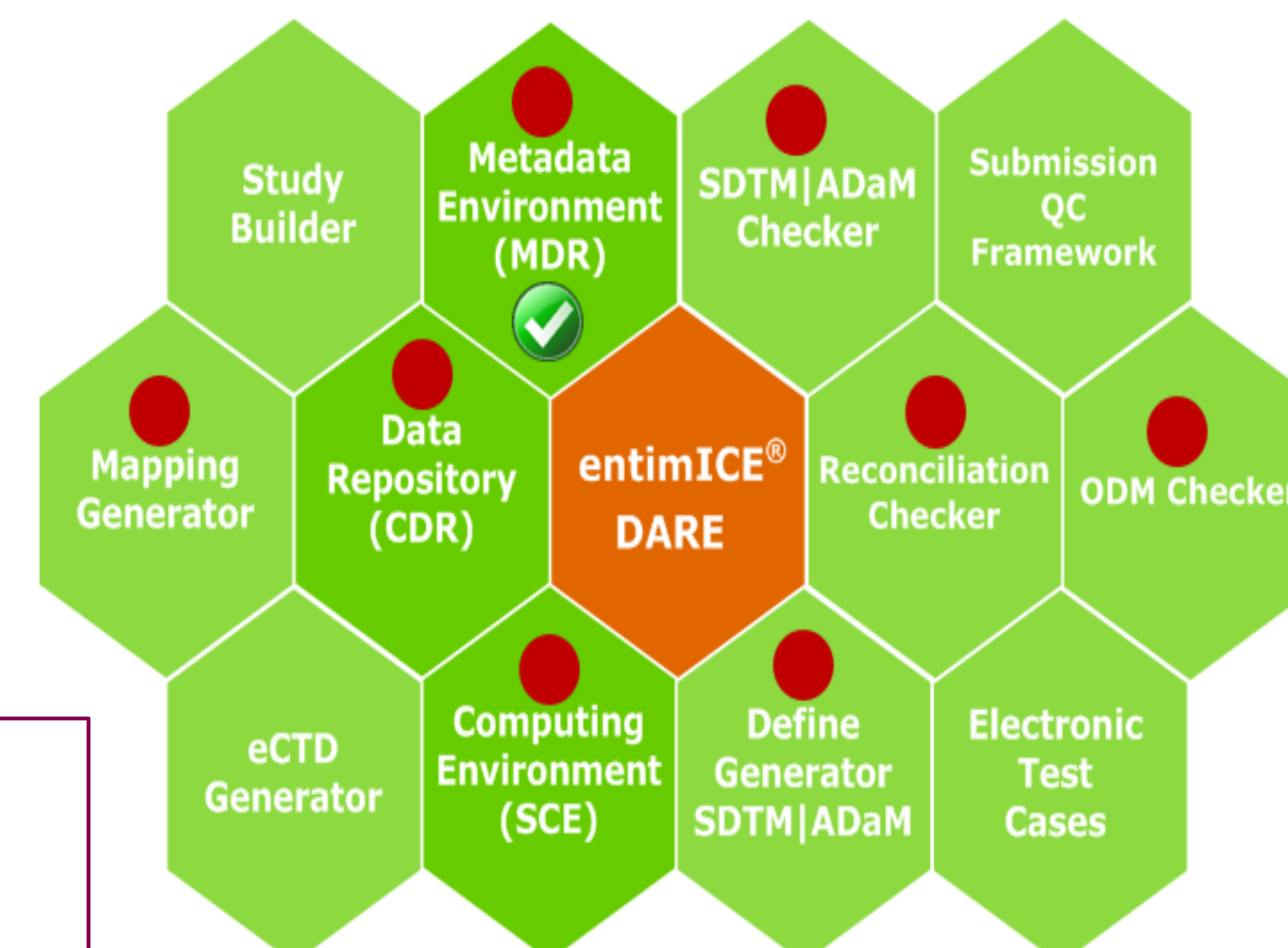
SHAREPOINT CHALLENGE AND SHIFTING TO ENTIMICE-AZ SYSTEM Currently all AstraZeneca standards are stored in excel spreadsheets by domain on SharePoint. This is quite challenging and difficult, when it comes to version control, reusing the standards and sharing with vendors

To overcome this challenge AstraZeneca has launched the Integrated Clinical Analysis & Reporting Environment (iCARE) program which benefits ECD for managing, monitoring and evaluating drug development and to test assumptions. The iCARE environment has three components called **EntimICE-AZ**, Clinical Trial Data Storage (CTDS) and Master List of Clinical Studies (MLCS)

CLINICAL DATA REPOSITORY (CDR) EntimICE-AZ offers a completely new analytical experience for statisticians and data scientists. EntimICE-AZ is able to integrate even Real World Evidence data as well as other data sources like safety data into clinical analysis. The highlights of CDR are

- Fast load performance
- Data privacy and data restrictions
- Configurable and robust governance
- Metadata and standards re-usability
- Flexibility through dual storage concept

entimICE-AZ Integrated Clinical Environment



ENTIMICE-AZ

The name entimICE is the abbreviation for the “Entimo Integrated Clinical Environment”. It is a system containing standards metadata repository (SDMR), Standards governance, and Analysis & reporting tools. The EntimICE-AZ will be organised into

- Standard Meta data Repository
- Clinical data Repository
- Computing environment
- Standards Request System
- Dictionary management
- Define Generator SDTM & ADaM

STANDARD METADATA REPOSITORY (SDMR)

All AstraZeneca science units will use the EntimICE-AZ standards hierarchy, the standards metadata repository. Access will be granted to the standards hierarchy based on named users. All user who have access to system will also have read-only rights to all standards production directories. A separate hierarchy following the same folder structure will be created for the TA and drug project specifications

COMPUTING ENVIRONMENT (PROD AND DEV)

EntimICE-AZ is a metadata driven statistical computing environment with a tightly integrated data and metadata repository. The goal of the solution is to provide a unified programming interface for SAS, R with access to integrated flows of data. The highlights are:

- Development and Production environment features
- Unified and efficient programming
- Easy interfacing to source and tools
- Central library of reusable standards
- Transparent governance process

STANDARDS REQUEST SYSTEM

EntimICE-AZ request tool contains three different types of request: common standard related to data structures or output TLF. In addition dictionary requests are also allowed in the system. Within EntimICE-AZ, any ECD requests for a study or AstraZeneca or TA standard should be submitted in the request tool. The TA or Corporate change request will contain a description of the proposed change. Project specific ECD requests can be implemented before formal approval within the EntimICE-AZ system

CONCLUSION EntimICE-AZ is a complex system with ample number of new components for AstraZeneca to embrace. It is envisaged that the knowledge, process and efficiencies needs to be built over a longer period of time. The implementation of the system will therefore be phased having overlapping solutions until the complete EntimICE-AZ Suite content has been developed and deployed into the organisation