



Enhancing the Productivity of Analysis & Reporting through Collaborative Innovation



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Purpose: Pfizer is currently evaluating sharing our enterprise CDISC Data Analysis & Reporting System (CDARS) and our standard CDISC clinical reporting software as an industry solution to improve quality and decrease costs in the reporting of clinical data ultimately leading to quicker approval of new drug treatments for patients

Business drivers:

- Moving to CDISC is an opportunity to introduce CDARS and Pfizer Clinical Algorithms to drive industry framework
- Collaborate on future enhancements to CDARS and the development of CDISC standard clinical reporting software
- There is no benefit to Pfizer to go down this path alone
- Align the industry to one system and standard safety and efficacy reporting software will improve future co-promotes and collaborations
- CDARS provides transparency to the Clinical Project Team
- Potentially open up the environment to allow for direct access to data, software, and TLF's through a Regulatory Portal – complete transparency in the conduct and reporting of our clinical data

CDARS

CDISC Data Analysis Reporting System



CDARS



GDMS



SAS Web Tools



Pfizer Data Standards Catalog

Migration Links

Reporting Event Tracker

Project Documentation

Linux/SAS Migration Checklist(s)

Weekly Status Meetings

Project Roster, Stakeholders and Change AgentsFAQs

Get Support

Request Access

Business Support

System Support

Important Links

How do I access CDARS?

CDARS Training Materials

PDS Data Mapping

Announcements

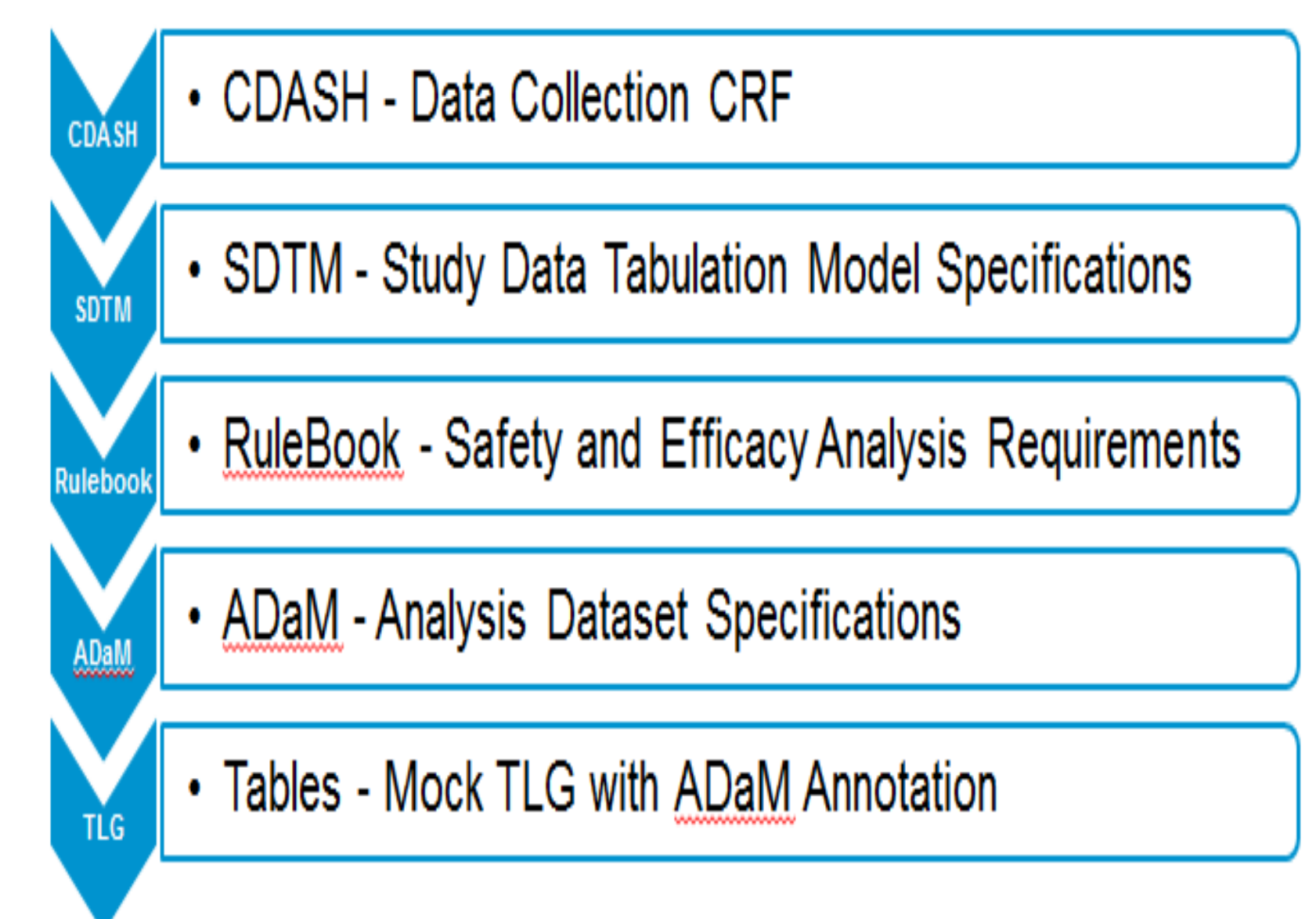
Calendar

FAQs

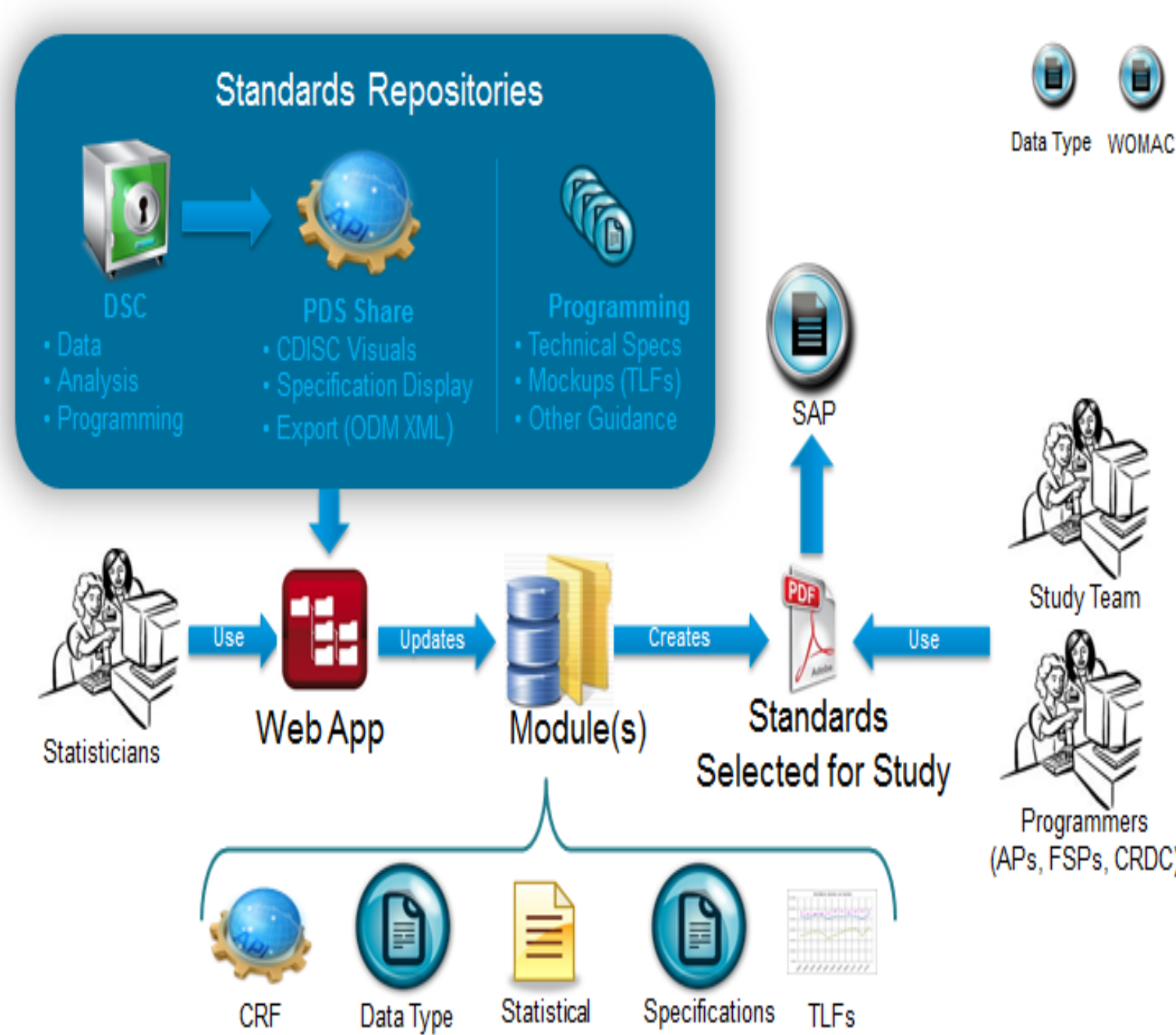
Programming Standards at Pfizer

- Culture of Programming Standards started at Pfizer more than 20 years ago.
 - Goal is to maximize re-usability of SAS programs
- Hierarchy of SAS Codebase ("SAS AUTOs")
 - SAS Global Library ("System Level code")
 - Project
 - Submission
 - Protocol
- Programming Standards Group manages "System Level code" and works with Project/Study Level programmers to make sure "System Level code" gets leveraged.
- Study/Project Level Programmers use "System Level code"
 - Goal is to minimize code development at Project/submission/protocol

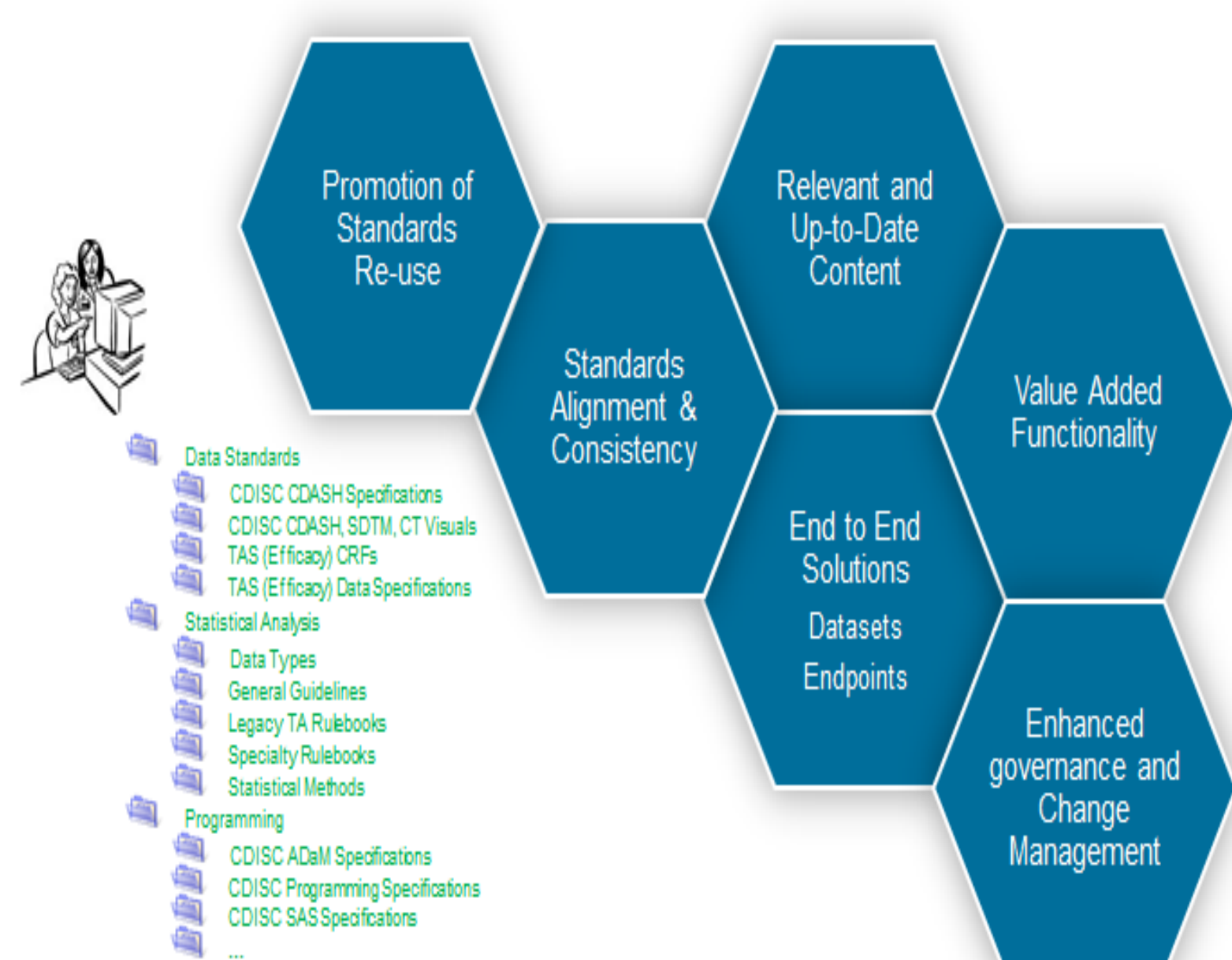
Pfizer's Approach – "End to End" CDISC Implementation



Rulebook Modularization Overview



Critical Success Factors



Since 1997, CDARS has been Pfizer's primary validated / 21 CFR Part 11 compliant analysis and reporting environment that ensures speed, efficiency, and quality in the generation of Analysis Datasets and Tables, Listings, and Figures used to support all Therapeutic Areas and Business Units.

Clinical Data

- CAL/CSDW
- Oracle Clinical
- Data Labs (PeCS)
- Argus Safety
- AP/CRO systems
- Unstructured data

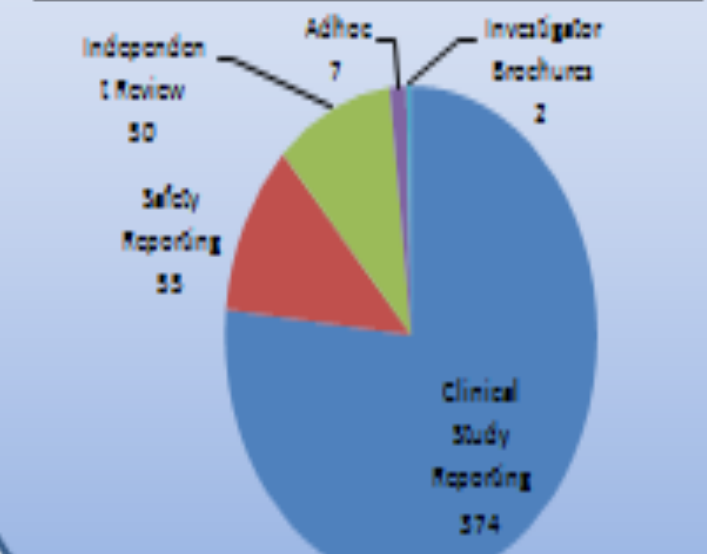
Clinical Analysis

- Standard safety and efficacy regulatory clinical reporting software based on Pfizer proprietary and CDISC standards

Clinical Reporting

- Supports world wide regulatory submission reporting (FDA, EMA, PMDA and more)
- Rapid Response and Exploratory Analyses

2014 CDARS Reporting Activity



CDARS – Reporting Repository

- ~ 700 Drug Programs
 - 24,000 Clinical Studies
- 13,000 Reporting Events/Submissions
- 50TB of Data
- ~3000 users (500 daily)