

The Coming Revolution in Clinical Trial Management Systems

By Norman M. Goldfarb

The National Cancer Institute (NCI) Center for Bioinformatics is leading a massive project – caBIG™ (cancer Biomedical Informatics Grid™) – to build an Internet-based infrastructure to facilitate cancer research. With over 800 participants from more than 80 academic, government and industry organizations, caBIG will revolutionize the conduct of cancer research and eventually all biomedical research in the United States and worldwide.

Unlike many large software development projects, caBIG is already bearing fruit, with modules in various stages of design, development, pilot testing and production. Because of its inclusive organization and open-source architecture, caBIG will accommodate current and future software applications into a single cohesive, standards-based infrastructure.

Within caBIG, the CTMS (Clinical Trial Management Systems) group is developing software tools to streamline the operational (non-scientific) aspects of clinical research. The purpose of this article is to present a coherent picture of these tools and their relationships. Table 1 lists the CTMS component systems and their current status, along with three components from the related NCI CRIX (Clinical Research Information Exchange) project. Diagram 1 describes their relationships. Because of the number and complexity of the component systems, the information in this article is highly summarized and simplified. For more detailed information, visit <https://caBIG.nci.nih.gov>. All interested parties are welcome to participate free of charge.

Table 1. caBIG CTMS Component Systems

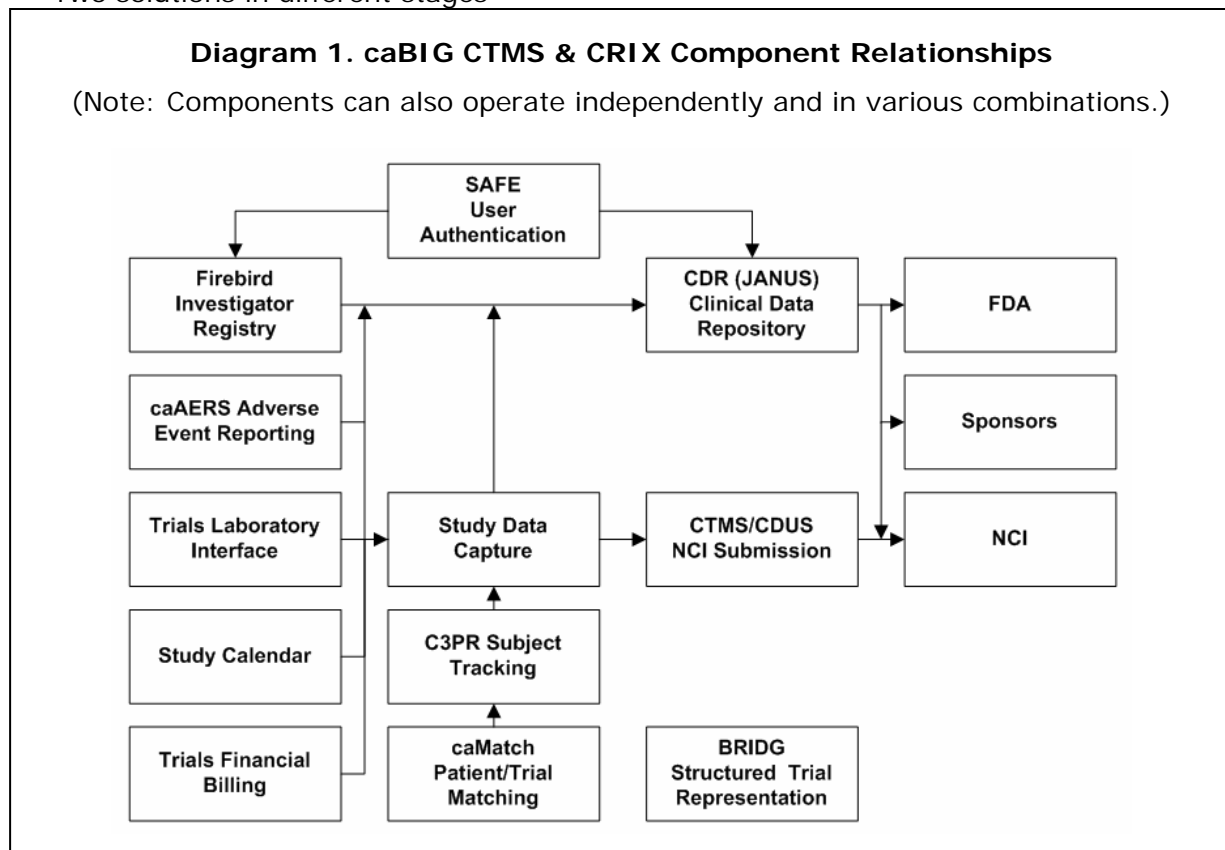
Component	Function	Status
Firebird (Federal Investigator Registry for Biomedical Research Data)*	System for collecting, reviewing and submitting FDA Form 1572s electronically	Pilot Testing
CDR (Clinical Data Repository)*	Database of clinical trial data in a standardized JANUS format for submission to FDA	Development
BRIDG (Biomedical Research Integrated Domain Group Model)	Structured representation of the clinical trial lifecycle	Development
SAFE (Secure for Everyone)*	User authentication and digital signature system licensed from SAFE Foundation	Pilot Testing
Study Data Capture	Clinical trial data capture and information management system. C3D (Cancer Central Clinical Database) is the first example	Production/Development**
CTMS/CDUS (Clinical Trial Monitoring Service/Clinical Data Update System) Reporting	C3D tool for collecting and translating data from data collection systems into required formats for submission to NCI.	Production

Study Calendar	System for scheduling and tracking study events such as screening, randomizing and monitoring subjects	Requirements Definition
caAERS (Cancer Adverse Events Reporting System)	System to collect, process and report adverse events that occur during clinical trials	Development
C3PR (Cancer Central Clinical Participant Registry)	System for tracking clinical trial subjects	Pilot Testing
caMatch	System for matching patients to clinical trials	Development/ Pilot Testing**
Trials Financial Billing	System for managing and monitoring clinical trial expenditures and billing compliance	Requirements Definition
Trials Laboratory Interface	System that translates laboratory data from multiple systems and in multiple formats into common standards for entry into Study Data Capture systems	Requirements Definition

Notes:

* CRIX project

** Two solutions in different stages



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