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## Biomedical Research Business Architecture Model Frequently Asked Questions

For background, you may reference the presentation on the Business Architecture Model at the CTMS Face to Face in Albuquerque, NM, April 2008. [Business Architecture Model Overview](#)

### General BAM FAQ's

#### What is the business architecture model (BAM)?

The business architecture model is a top down approach to build a framework for the domain of clinical research and layout the processes on how to identify and capture all the business use cases in a consistent manner.

### **What are the goals of the business architecture model?**

- To create a process to communicate biomedical research activities identified in the Business Architecture Model between the business analysts, business liaison, development liaison and the development team.
- To reduce the number of gaps between the existing clinical research requirements and existing applications.
- Manage changes in requirements from the business and development side using the an established process.
- Apply the identified interoperability scenarios of the clinical research business process to the applications.
- Harmonize the identified components of the biomedical research business process with existing resources, caBIG® initiatives, and extramural activities. Examples include Cancer Data Standards Repository (caDSR), Biomedical Research Integrated Domain Group (BRIDG), Health Level 7 (HL7) and the Clinical Data Interchange Standards Consortium (CDISC).
- To align future development activities with the identified biomedical research business process.

### **When did the business architecture modeling activity start?**

The business architecture modeling activity started in October of 2007.

### **Why did the business architecture modeling activity start?**

A team of analysts and clinical trials Subject Matter Experts from the caBIG® community were tasked with identifying interoperability scenarios in clinical trials management. As the team began this work, it became apparent that a commonly agreed upon framework for clinical trials was required to facilitate identification of scenarios. This team worked diligently to flush out the foundation of the model, and it was then brought to the CTMS Workspace community for review and elaboration through the Special Interest Group infrastructure.

### **How do the activities going on in the BAM relate to the caBIG® Clinical Trials tools?**

As business use cases are identified, analyzed, and completed in the business architecture model, the development team will take those business use cases, convert them into functional requirements and develop applications to meet the business needs of the stakeholders. Therefore processes identified in the BAM will align directly with the caBIG® Clinical Trials tools.

## How can I get involved with the activities in the business architecture mode?

There are many ways you can get involved with business architecture modeling activity:

- Contact our main CTMS Workspace email at [CTMS\\_Workspace@bah.com](mailto:CTMS_Workspace@bah.com)
- Visit the [Business Architecture Model Wiki Page](#).
- Post a request on the [Business Architecture Model Feedback](#).
- Attend any of our working group meetings. Please visit our [CTMS Workspace Calendar](#) to view dates and times of our working group meetings.

## BAM Activities FAQ

### How are the activities broken down in the business architecture model?

The activities are broken down into the four stages of biomedical research:

- **Plan Study**: Develop, document and maintain the scientific, regulatory, financial, legal and logistical (including the protocol processes and resources) aspects of a protocol.
- **Initiate Study**: Complete the regulatory, financial and logistical requirements to activate the study for site participation and open the study at the sites for subject enrollment. This applies to both the Coordinating Center and Participating Sites. This includes all updates (amendments) to the study.
- **Conduct Study**: Includes all the activities involved in execution of a study, i.e., from the time the study is made available for enrollment until end of study when data collection is complete.
- **Report and Analyze Study**: Develop and provide an organized collection of information to authorized stakeholders in support of execution of the protocol statistical plan, subject safety and regulatory requirements.

### What are the activities in business architecture model?

#### *Use Case Development*

To begin developing use cases, Business analysts receive the prioritized use cases from CTMS Management and SMEs from the community. Analysts then facilitate working group meetings to vet out those use cases. Note each working group follows a standard approach to facilitate the meetings, however the activities and the identified elements in the working group sessions may be implemented differently based on goal of the use case and the preferences of those attending the working group meetings. In the working group meetings, analysts

## BAM\_FAQ

- Meet weekly (or more) to define the requirements
- Work with Co-Chair / work group lead
- Prepare plans to facilitate meeting
- Facilitate meeting and gather feedback from user community

As those Use Cases are further defined, analysts conduct Special Interest Group (SIG) meetings to gather additional feedback on the use cases. In the SIG meetings, analysts

- Meet monthly to review the progress of the working group
- Prepare plans to facilitate meeting
- Facilitate meeting and gather feedback from use community

Once those Use cases are completed, they are sent to the Governance team for approval. If they are approved by the governance team, they are then given to the Composite Architecture Team (CAT) to determine if this is a service or application. Once the CAT completes their activities, the NCI will determine to either move forward or not move forward on the application.

### ***Static Domain BRIDG Alignment***

- The BRIDG will provide a shared view static semantics that collectively define the domain of clinical and pre-clinical protocol-driven research and its associated regulatory artifacts. Data elements identified in the BAM use cases are harmonized with BRIDG to provide a set of applied static elements in the biomedical research process.

### ***Gap Analysis***

- BAM will be aligned with the existing applications of the caBIG® Clinical Trials Suite. This involves performing a harmonization of use cases identified at the system level which belong at the BAM level, and business functionality gap analysis which includes reviewing the application to ensure all required business activities identified in the BAM are represented, as applicable and appropriate, in the application. Also, aligning the business functions captured at the system level analysis with the BAM. This effort aims to resolve gaps between the business and the business function automated in an application.

### ***Case Report Form Alignment***

- As part of use case definition, use case working groups will indicate where in the biomedical research business process specific Case Report Form modules are applicable. This alignment may not be accomplished in the first iteration of use case definition as the CRF modules are also in development and may not yet have been completed. The purpose of this alignment is to facilitate CRF module adoption and adaptation into automated processes. The intent is to ensure all working efforts are in alignment and applicable work is leveraged and linked as appropriate.

### ***Reporting Variable Identification***

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## **What is BRIDG and how does it relate to the BAM?**

BRIDG provides a shared view of static semantics that collectively define the domain of clinical and pre-clinical protocol-driven research and its associated regulatory artifacts. As data elements identified in the BAM use cases, these elements are harmonized with BRIDG to provide a set of applied static elements in the biomedical research process

## **BAM Use Case FAQ**

### **What is a Use Case?**

A use case is a high level process of a collection of scenarios related to a goal.

### **What are actors in a Use Case?**

Actors are the roles people play at their organization in relation to the activities they perform.

### **What is a precondition in a Use Case?**

A precondition defines all the conditions that must be true before the process identified in the use case can begin.

### **What is a post condition in a Use Case?**

A post condition describes what the end result will be for the process identified in the use case.

### **What is a Storyboard?**

A story board is a summary section describing the sequence of scenarios that includes the goal and the principal actor.

**What is an alternate path?**

An alternate path is a secondary path or alternative scenario that is a variation of the identified process in the use case.

**What do the different levels of use cases represent (1,2, 3, 4)?**

A level 1 use case represents the highest level of a process. Based on the steps needed to satisfy that process, additional levels are created, each drilling down to more detail to eventually satisfy level 1 of the use case. A use case does not have a set number of levels; it is dependent upon how much detail needs to be documented to reach the goal.