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## Biomedical Research Business Architecture Model

The Biomedical Research Business Architecture Modeling (BAM) activity is highly collaborative and leverages the knowledge of domain experts that participate in the caBIG® [Clinical Trials Management Systems Workspace](#).

The business stakeholder scope of the model spans the [National Cancer Institute](#), [Cooperative Groups](#), Participating Sites, and the broad clinical research community. The objective of this effort is to identify the business use cases (activities), analyze the use cases and processes, and build a comprehensive business architecture model of the clinical research domain.

It 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. This is a large task and different aspects of the model are broken out for working group review with a community lead on each portion. The modeling effort is facilitated by analysts who work to harmonize content provided by subject matter experts with existing resources and other caBIG® initiatives such as the Cancer Data Standards Repository ([caDSR](#)), Biomedical Research Integrated Domain Group ([BRIDG](#)), as well as extramural activities like Health Level 7 ([HL7](#)) and the Clinical Data Interchange Standards Consortium ([CDISC](#)).

It is important to note that this effort is following an iterative methodology. It is not expected that each aspect of the model, or the entire model, will be a complete representation of the clinical trials process at first brush. Rather, the CTMS Workspace aims to achieve, through content capture, review, validation, and refinement, a model that at a high level represents the process, interactions, and interoperability that occur in the planning, initiation, and conduct of a clinical trial. From this model, the workspace aims to facilitate gap analysis of functionality in the current [caBIG® Clinical Trials Suite](#) and map caBIG® solutions to clinical research business needs.

## Business Architecture Documentation

## Frequently Asked Questions

For more information on business architecture modeling, please consult our Introduction to Biomedical Research Business Architecture Model page: [FAQ](#)

## Glossary

For more information on terms and definitions on the Biomedical Research Business Architecture Model, please consult our Biomedical Research Business Architecture Model Glossary of Terms and Definitions page: [Glossary](#)

## CTMS Biomedical Research Business Architecture Model

We welcome you to review the use cases in development.

The model is represented in the wiki for ease of review - this is a work in progress: [Biomedical Research Business Architecture Model Content](#)

## Modeling Activity Areas

Please click on the links below to reach information on the stages of the biomedical research process:

- [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. This applies to both the coordinating center and participating sites.
- [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.
- [Enterprise Common Resources](#): .

## Modeling Activity Status

The Biomedical Research Business Architecture Model use cases are in varying stages of development, use case statuses are defined below:

- Original: Use cases as defined by the CTMS Interoperability subject matter experts in the inception of the Business Architecture Model.
  - Placeholder: Use cases identified during a working group that are outside the scope of the working group.
  - Working Group: Use cases that are currently being defined in a CTMS workspace working group.
  - CTMS Workspace Review: Use cases that are being reviewed by the CTMS workspace community.
  - CTMS Workspace Reviewed: Use cases that have been reviewed by the CTMS workspace community.
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### Submit Feedback

Please submit feedback, comments, and questions about the business modeling activities through the Clinical Trials Management Systems (CTMS) General discussions forum.

- [Business Architecture Model Feedback](#)
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### Templates

[Business Architecture Model Feedback](#)

[CTMS Workspace Calendar](#)