

Knowledge Acquisition Session Report Common Data Elements

KA Session Date: 1/31/02

Session Topic: Common Data Elements (CDE) Actors and Business Use Cases for the Common Data Elements Model

Knowledge Analysts: ScenPro, Inc.

General Topic Area

This document contains representations of the Actors and Business Use Cases for the Common Data Elements Model project. This Use Case document consists of:

- List of Actors
- Summary of the Business Use Cases
- Business Use Case Diagrams
- Text of the Business Use Cases
- Activity Diagrams for the Business Use Cases

List of Actors



CDE Committee



CDE Support Staff



Clinical Trial Tool Developer



Clinical Trials
Support Unit



Clinician



Concept Committee



Data Manager



Food and Drug
Administration



Institutional Review Board



CDE Reviewer



Patient



Pharmaceutical
Company



Principal Investigator



Protocol Coordinator



Sponsor



Statistician

Actor	Description
Principal Investigator (PI)	A physician with the primary responsibility for the development and submission of a clinical trial protocol and the conduct of the resulting clinical trial.
Patient	An individual enrolled in a clinical trial investigating the treatment or prevention of cancer. The patient must meet specific eligibility criteria defined in the clinical trial protocol.
Clinician	A physician, research nurse, physician's assistant, or technician who treats patients using the treatment regimen prescribed in a clinical trial protocol and who collects the required data.
Data Manager	An individual at a cooperative group or cancer center who designs clinical trial case report forms and manages the data returned on those forms.
Statistician	An individual at a cooperative group or cancer center who determines the statistical design required for a clinical trial and who analyzes clinical trial data once it has been collected and returned.
Protocol Coordinator	An individual at a cooperative group or cancer center who coordinates the development of a clinical trial protocol and who may in fact write part of the protocol or adapt parts of it from previous protocol documents.
Pharmaceutical Company	An organization that investigates, develops and markets chemotherapeutic and chemopreventive agents. Pharmaceutical companies provide drugs for clinical trials.
CDE Committee	A committee convened by NCI, consisting of experts in clinical trials for a particular type of cancer (breast, prostate, GI, etc.). With assistance from NCI personnel and CDE Support Staff, the committee defines a commonly used set of terminology for data relating to that type of cancer (Common Data Elements). This committee also evaluates proposed new elements for inclusion in the terminology.
CDE Reviewer	An individual at the National Cancer Institute who evaluates whether submitted clinical trial documents (protocols, case report forms) comply with common data element terminology.
Sponsor	An organization that solicits, approves, and pays for a clinical trial. The sponsor for a clinical trial will typically be a division of NCI, a pharmaceutical company, or a cancer center. NCI divisions will sponsor most trials involving Common Data Elements. The clinical trial sponsor will usually handle regulatory filings for the clinical trial.
Clinical Trial Tool Developer	A software developer attempting to create and implement information technology to support some aspect of clinical trial development or management.
Institutional Review Board (IRB)	A committee for a cancer research institution that must review and approve all clinical trial activity at that institution. Institutions with large numbers of clinical trials usually have multiple Institutional Review Boards.

Actor	Description
Food and Drug Administration (FDA)	A federal organization that regulates all aspects of food and drug production, including the development and conduct of clinical trials.
CDE Support Staff	A group of individuals knowledgeable about common data elements and cancer research who help CDE committees and NCI CDE Reviewers carry out their tasks. CDE Support Staff may organize CDE Committee meetings, gather information for CDE Reviewers, and update information in the CDE database.
Concept Committee	A committee at a cooperative group or cancer center that evaluates possible clinical trial topics and determines which ones should be pursued for development into protocols.
Clinical Trials Support Unit (CTSU)	An NCI-sponsored consortium with the mission of improving cross-group patient accruals, streamlining clinical trial data entry/collection, and standardizing membership rosters and IRB approvals. The consortium consists of Oracle Corp., Westat, Inc., and the Coalition of National Cancer Cooperative Groups.

Summary of the Business Use Cases

1.0 Participate in Clinical Trial

- 1.1. Patient enrolls in clinical trial.
- 1.2. Clinician administers clinical trial treatment.
- 1.3. Patient receives clinical trial treatment.
- 1.4. Patient maintains quality of life.
- 1.5. Patient provides clinical trial data.
- 1.6. Clinician collects clinical trial data.

2.0 Secure Clinical Trial Funding

- 2.1. PI writes clinical trial concept
- 2.2. Concept Committee prioritizes clinical trial concept
- 2.3. PI writes LOI/concept/proposal
- 2.4. PI submits LOI/concept/proposal to Sponsor
- 2.5. Sponsor approves LOI/concept/proposal
- 2.6. PI develops clinical trial protocol
- 2.7. PI submits clinical trial protocol to Sponsor
- 2.8. Sponsor approves clinical trial protocol
- 2.9. FDA approves clinical trial protocol
- 2.10. Sponsor funds clinical trial

3.0 Conduct Clinical Trial

- 3.1. PI gives instructions to Clinicians
- 3.2. Clinicians enroll Patients
- 3.3. Clinicians treat Patients
- 3.4. Patient provides clinical trial data
- 3.5. Clinician collects clinical trial data
- 3.6. PI responds to Clinician and Sponsor inquiries
- 3.7. PI reports adverse events to Sponsor
- 3.8. Clinician completes patient accrual
- 3.9. Data Manager processes clinical trial data
- 3.10. PI closes clinical trial
- 3.11. Statistician analyzes clinical trial data
- 3.12. Statistician reports clinical trial results to PI
- 3.13. PI reports clinical trial results to Sponsor

4.0 Carry Out Clinical Trial Activities

- 4.1. Clinicians enroll Patients
- 4.2. Clinicians treat Patients
- 4.3. Patients receive treatment
- 4.4. Patient provides clinical trial data.
- 4.5. Clinician collects clinical trial data
- 4.6. Clinicians prepare clinical trial reports for PI and Sponsor
- 4.7. Clinician reports adverse events to PI

5.0 Develop Case Report Forms

- 5.1. Data Manager evaluates the protocol's data collection needs
- 5.2. Statistician defines data analysis needs for the Data Manager
- 5.3. Data manager drafts case report forms for protocol
- 5.4. Data manager guides case report forms through internal approvals

- 5.5. Data Manager revises case report forms as required by internal reviews
- 5.6. Forms Technician creates finished version of case report forms
- 5.7. Data Manager reviews case report forms for final edits
- 5.8. Data Manager sends internally approved case report forms to Protocol Coordinator

6.0 Provide Statistical Expertise for Clinical Trial

- 6.1. Statistician reviews draft clinical trial concept
- 6.2. Statistician develops experimental design for clinical trial
- 6.3. Statistician develops analysis plan for clinical trial
- 6.4. Statistician identifies accrual needs for ancillary studies
- 6.5. Statistician determines factors to include in eligibility criteria
- 6.6. Statistician provides input to Data Manager on case report form items needed
- 6.7. Statistician sends statistical design information to PI
- 6.8. PI incorporates statistical design information into protocol

7.0 Develop Protocol Documents

- 7.1. Protocol Coordinator incorporates boilerplate items into protocol document
- 7.2. Protocol Coordinator pulls sections from previous protocols for re-use
- 7.3. Protocol Coordinator incorporates new items into the protocol document
- 7.4. PI provides guidance on protocol development
- 7.5. Protocol Coordinator communicates with protocol development participants about protocol
- 7.6. Protocol Coordinator incorporates suggested changes into the protocol document
- 7.7. PI reviews and approves the final protocol document
- 7.8. PI submits the protocol to the Sponsor
- 7.9. Sponsor approves the protocol

8.0 Develop New Common Data Elements

- 8.1. CDE Committee assembles resources
- 8.2. CDE Support organizes the resources
- 8.3. CDE Committee sorts through the resources
- 8.4. CDE Committee organizes data elements
- 8.5. CDE Committee reduces data elements
- 8.6. CDE Committee links data elements to existing standards
- 8.7. CDE Support organizes CDE Committee output
- 8.8. CDE Committee revises data elements
- 8.9. CDE Committee finalizes Common Data Elements
- 8.10. CDE Support manages publication of new Common Data Elements

9.0 Evaluate Proposed Changes/Additions to Common Data Elements

- 9.1. CDE Committee reviews proposed CDE changes/additions
- 9.2. CDE Support researches proposed CDE changes/additions for CDE Committee
- 9.3. CDE Committee estimates impact of proposed CDE changes/additions
- 9.4. CDE Committee approves proposed CDE changes/additions
- 9.5. CDE Support manages publication of revised Common Data Elements

10.0 Validate Case Report Forms

- 10.1. CDE Reviewer evaluates submitted case report forms
- 10.2. CDE Reviewer verifies that submitted case report forms are CDE compliant
- 10.3. CDE Reviewer communicates review results to Data Manager
- 10.4. CDE Reviewer approves case report form
- 10.5. CDE Reviewer identifies potential additional data elements from case report forms

- 10.6. CDE Reviewer identifies potential changes to data elements from case report forms

11.0 Approve Clinical Trials

- 11.1. Sponsor reviews letter of intent/concept/proposal
- 11.2. Sponsor approves letter of intent/concept/proposal
- 11.3. PI submits protocol
- 11.4. Sponsor reviews protocol
- 11.5. Sponsor approves protocol

12.0 Evaluate Clinical Trial Results

- 12.1. Sponsor reviews clinical trial results for primary study
- 12.2. Sponsor reviews clinical trial results for ancillary studies
- 12.3. Sponsor validates that questions of scientific interest have been answered
- 12.4. Sponsor assesses impact on future drug development
- 12.5. Sponsor identifies ideas for future research

13.0 Design Tools for Clinical Trials

- 13.1. CT Developer reviews the user requirements
- 13.2. CT Developer identifies available technologies
- 13.3. CT Developer identifies sources of data
- 13.4. CT Developer investigates the user environment
- 13.5. CT Developer identifies constraints
- 13.6. CT Developer conducts trade studies
- 13.7. CT Developer drafts a system architecture
- 13.8. CT Developer drafts a user interface

14.0 Approve Clinical Trial for the Institution

- 14.1. IRB reviews protocol document
- 14.2. IRB reviews data collection plan and case report forms
- 14.3. IRB conducts risk/benefit analysis
- 14.4. IRB approves protocol document and case report forms

15.0 Identify Clinical Trial Concepts for Development

- 15.1. Concept Committee reviews the concept summary
- 15.2. Concept Committee evaluates the concept summary against other concepts
- 15.3. Concept Committee assigns a priority to the concept

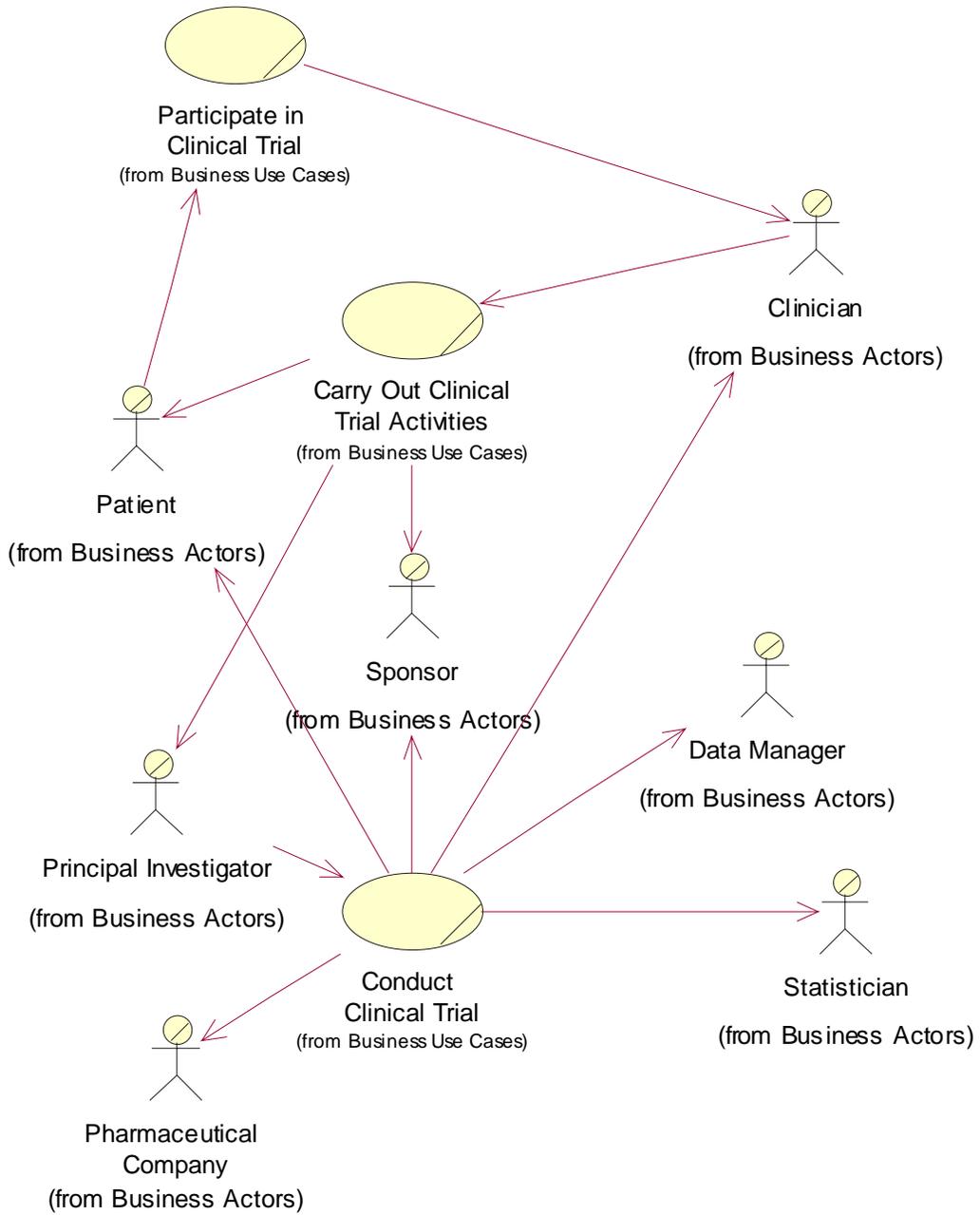
16.0 Support Remote Data Capture for Clinical Trials

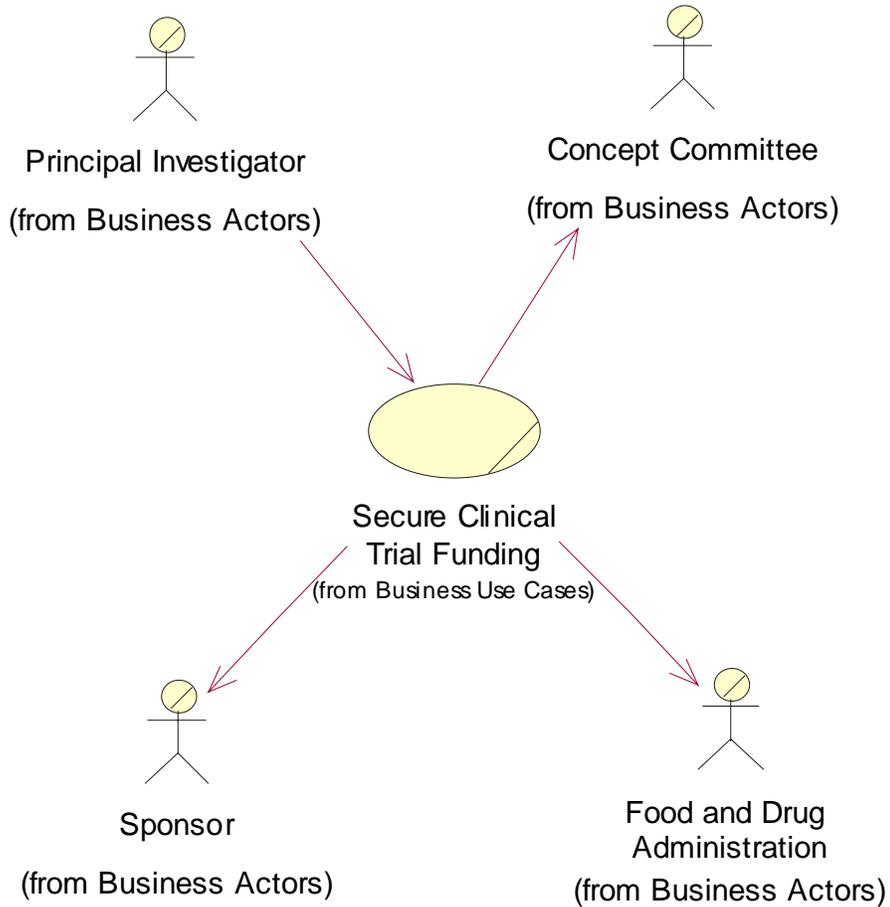
- 16.1. CTSU evaluates case report forms
- 16.2. CTSU renders case report forms into RDCMS
- 16.3. CTSU reconciles RDCMS with Common Data Elements

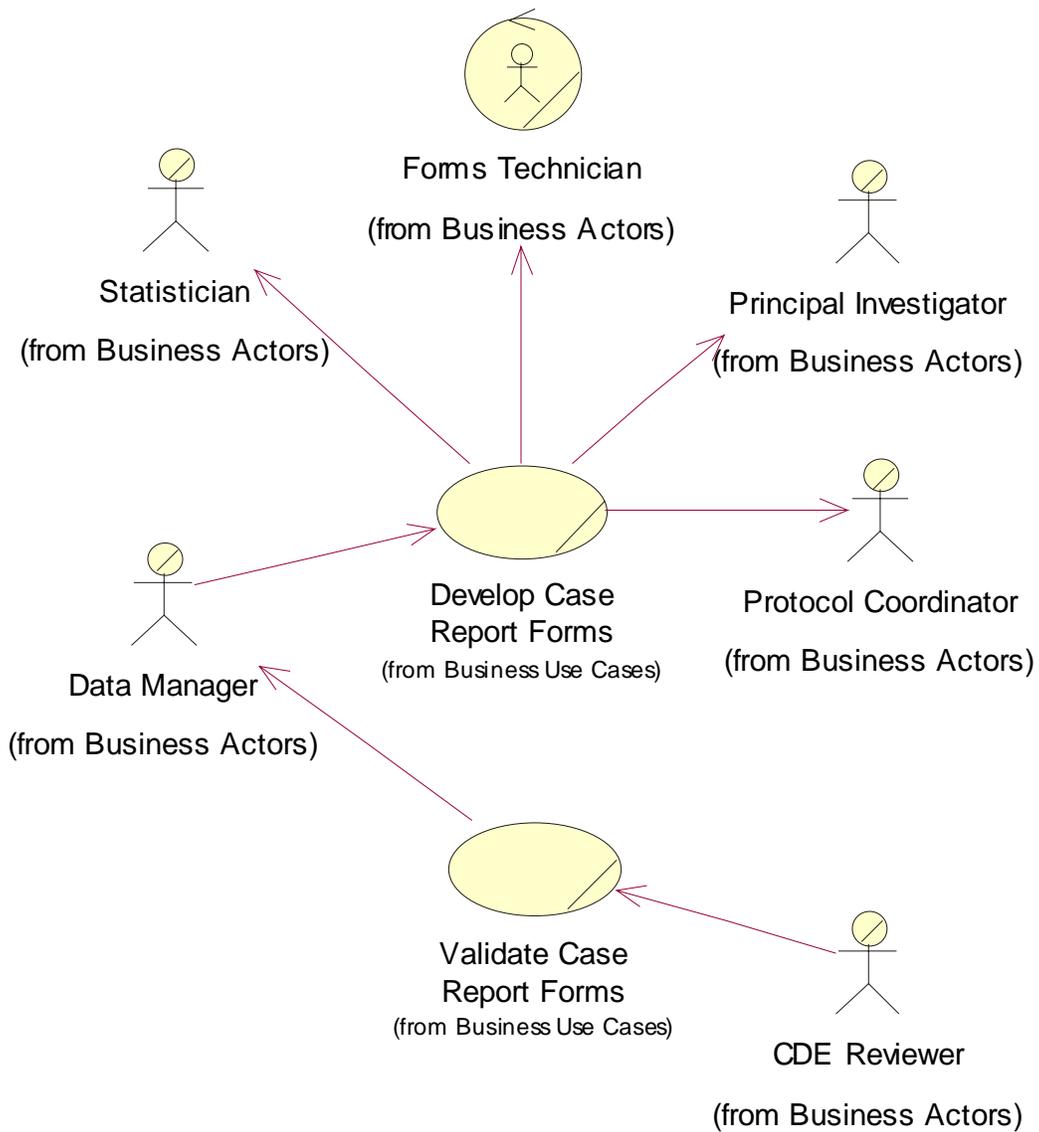
17.0 Analyze Study Data

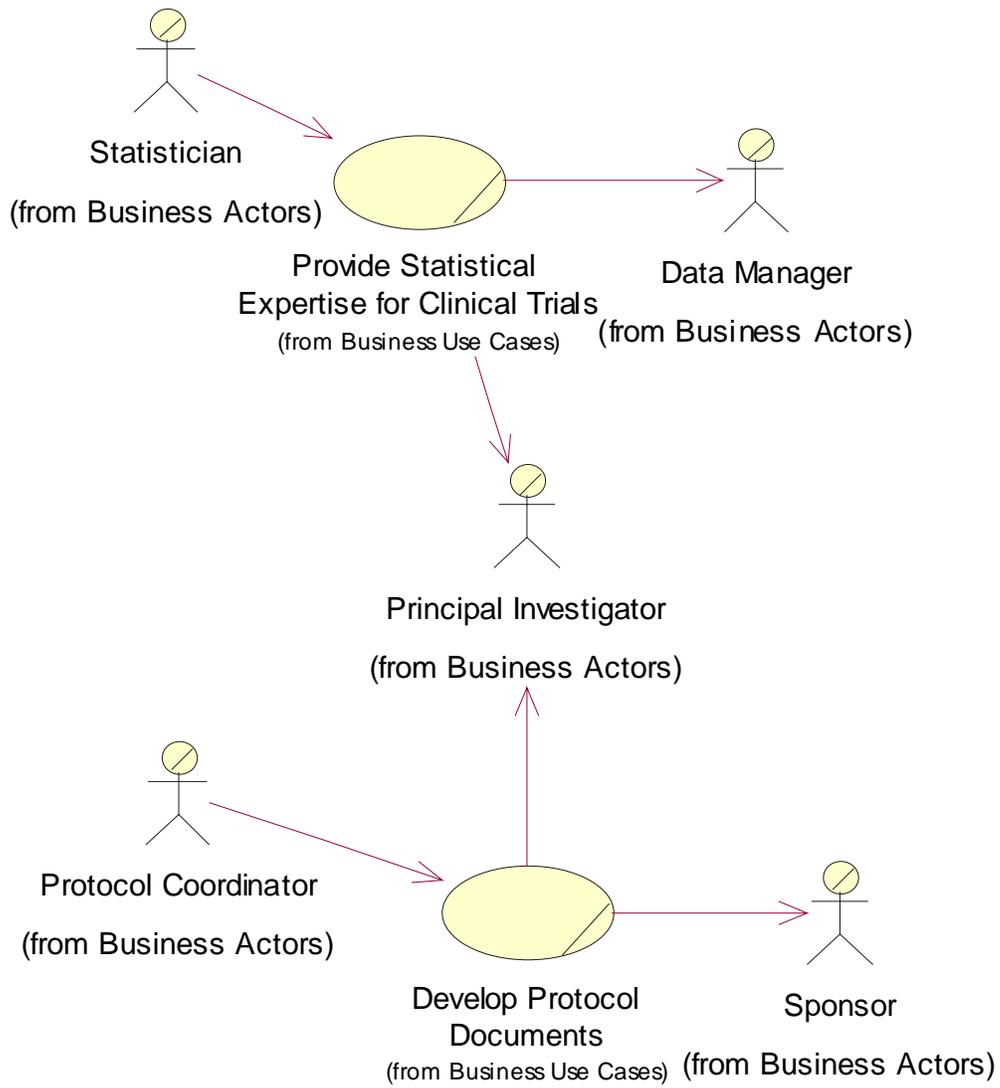
- 17.1. Statistician validates the collected data
- 17.2. Statistician performs data analysis
- 17.3. Statistician draws conclusions
- 17.4. Statistician reports clinical trial results to Principal Investigator

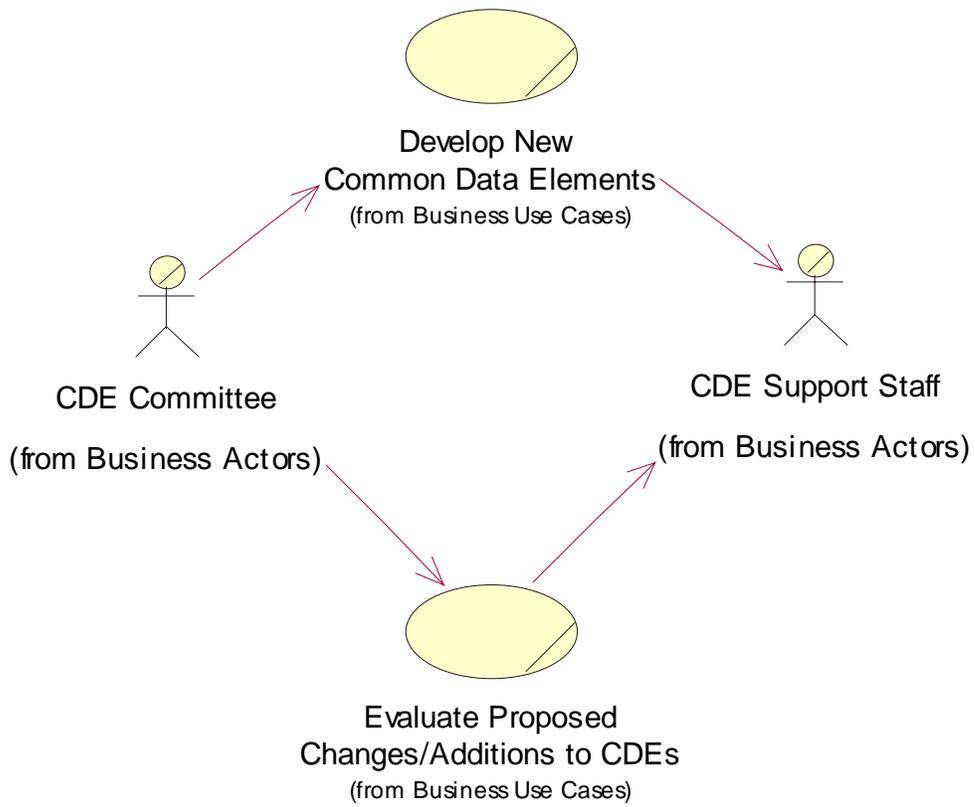
Business Use Case Diagrams

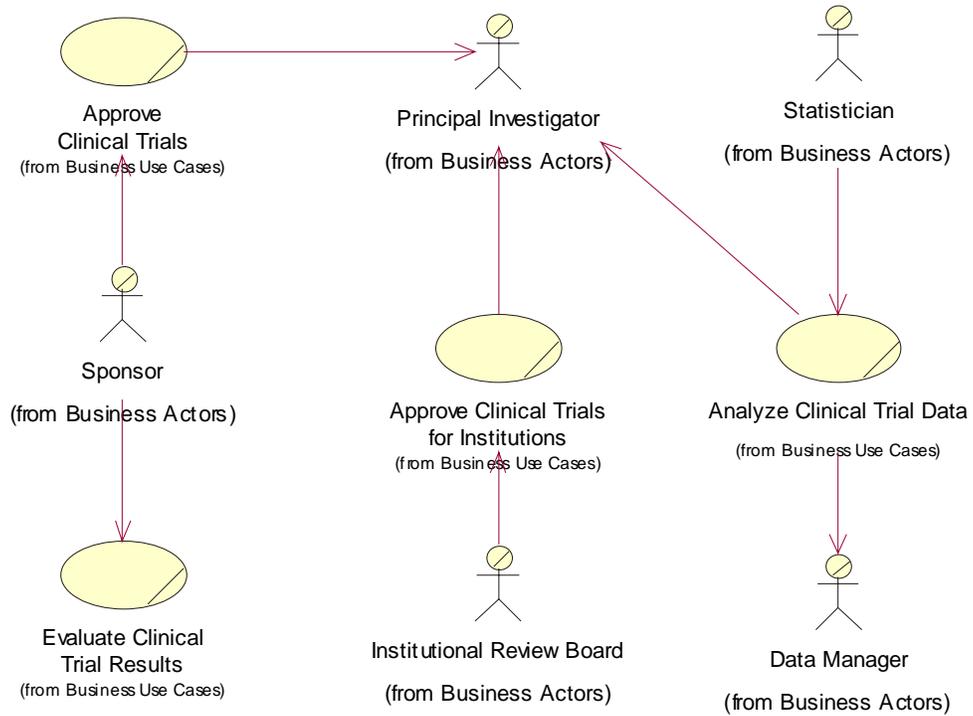


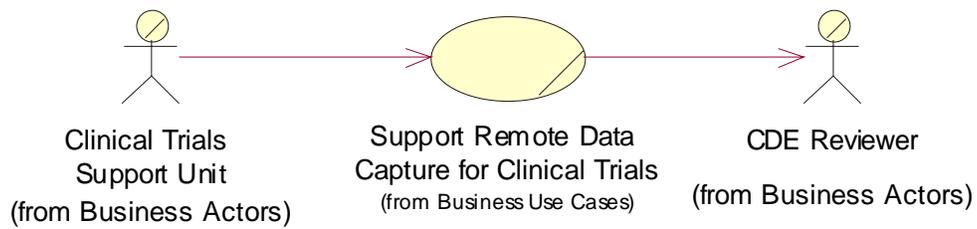
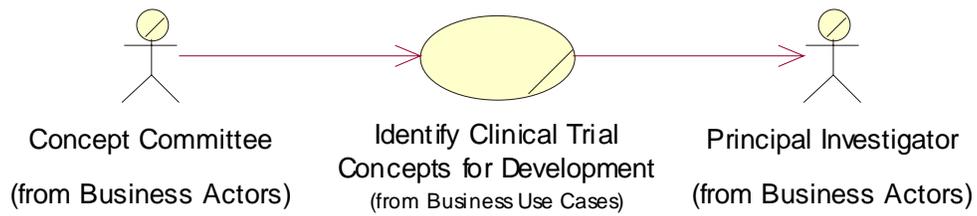
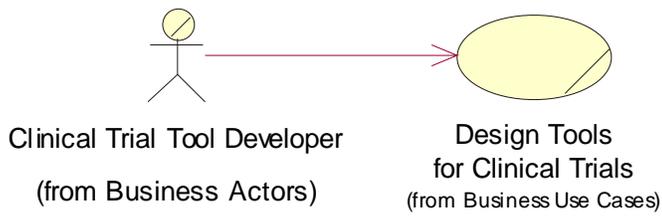












Text of the Business Use Cases

Use Case 1.0: Participate in Clinical Trial

Primary Actor: Patient

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

Stakeholders and Interests:

Patient—to receive safe and effective treatment

Principal Investigator—to answer questions of scientific interest

Clinician—to treat patients and collect the required data in compliance with the protocol

Food and Drug Administration—to ensure that federal regulations are obeyed and patients are protected

Institutional Review Board—to protect the patients and the interests of the research institution

Preconditions/Special Requirements:

1. Patient must have been diagnosed with cancer or meet other conditions indicating that he might be a valid participant in the clinical trial.
2. Clinical trial must be activated.

Minimal Guarantees: The patient's health and quality of life are not unnecessarily endangered. All federal and local regulations are followed.

Success Guarantees/Performance Goals: Patient receives the treatment prescribed in the protocol. All the correct data are collected to in order to answer the questions of scientific interest.

Trigger: Patient becomes interested in participating in a clinical trial.

Main Success Path/Workflow:

1. Patient enrolls in clinical trial.
2. Clinician administers clinical trial treatment.
3. Patient receives clinical trial treatment.
4. Patient maintains quality of life.
5. Patient provides clinical trial data.
6. Clinician collects clinical trial data.

Postconditions/Benefits:

1. Patient has received treatment.
2. Clinical trial data have been collected.

Extensions:

- 1.a Patient is ineligible for clinical trial
- 4.b Patient experiences adverse events
- 5.b Clinician validates that Patient may continue on clinical trial
- 5.b' Clinician removes Patient from clinical trial

Variations:

Use Case 2.0: Secure Clinical Trial Funding

Primary Actor: Principal Investigator

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

FDA—Food and Drug Administration

IRB—Institutional Review Board

PI—Principal Investigator

Stakeholders and Interests:

Principal Investigator—to answer questions of scientific interest

Food and Drug Administration—to ensure that federal regulations are obeyed and patients are protected

Sponsor—to fund research to answer questions of scientific interest

Institutional Review Board—to protect the patients and the interests of the research institution

Concept Committee—to ensure that the group or cancer center pursues the most promising clinical trial ideas

Protocol Coordinator—to develop scientifically useful clinical trial protocols that are likely to be approved with the lowest expenditure of time and resources

Preconditions/Special Requirements:

1. Principal Investigator has an idea for a clinical trial.

Minimal Guarantees: The Principal Investigator receives any reasons for disapproval of the clinical trial.

Success Guarantees/Performance Goals: The clinical trial protocol has been approved by the Sponsor, FDA and IRB. The Sponsor has funded the clinical trial.

Trigger: Principal Investigator begins developing clinical trial concept.

Main Success Path/Workflow:

1. PI writes clinical trial concept
2. Concept Committee prioritizes clinical trial concept
3. PI writes LOI/concept/proposal
4. PI submits LOI/concept/proposal to Sponsor
5. Sponsor approves LOI/concept/proposal
6. PI develops clinical trial protocol
7. PI submits clinical trial protocol to Sponsor
8. Sponsor approves clinical trial protocol
9. FDA approves clinical trial protocol
10. Sponsor funds clinical trial

Postconditions/Benefits:

1. Clinical trial protocol is approved
2. Sponsor has funded clinical trial.

Extensions:

- 4.a Sponsor requests revisions to clinical trial concept
- 5.a PI revises clinical trial concept
- 6.a PI submits revised clinical trial concept to Sponsor

- 4.b Sponsor disapproves clinical trial concept

- 6.c Sponsor requests revisions to protocol
- 7.c PI revises protocol
- 8.c PI submits revised protocol to Sponsor

6.d Sponsor disapproves protocol

9.e FDA requests revisions to protocol

10.e PI revises protocol

11.e PI submits revised protocol to Sponsor

9.f FDA disapproves protocol

Variations:

Use Case 3.0: Conduct Clinical Trial

Primary Actor: Principal Investigator

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

FDA—Food and Drug Administration

IRB—Institutional Review Board

PI—Principal Investigator

Stakeholders and Interests:

Patient—to receive safe and effective treatment

Principal Investigator—to answer questions of scientific interest

Clinician—to treat patients and collect the required data in compliance with the protocol

Food and Drug Administration—to ensure that federal regulations are obeyed and patients are protected

Sponsor—to fund research to answer questions of scientific interest

Data Manager—to collect the data required by the protocol

Statistician—to analyze the clinical trial results

Institutional Review Board—to protect the patients and the interests of the research institution

Preconditions/Special Requirements:

1. Clinical trial has been approved by Sponsor, FDA, and IRB.

Minimal Guarantees: The patient's health and quality of life are not unnecessarily endangered. All federal and local regulations are followed.

Success Guarantees/Performance Goals: Patient receives the treatment prescribed in the protocol. Planned Patient accrual for the clinical trial is achieved. All the correct data are collected to in order to answer the questions of scientific interest. Clinical trial results are obtained.

Trigger: Sponsor activates the clinical trial.

Main Success Path/Workflow:

1. PI gives instructions to Clinicians
2. Clinicians enroll Patients
3. Clinicians treat Patients
4. Patient provides clinical trial data
5. Clinician collects clinical trial data
6. PI responds to Clinician and Sponsor inquiries
7. PI reports adverse events to Sponsor
8. Clinician completes patient accrual
9. Data Manager processes clinical trial data
10. PI closes clinical trial
11. Statistician analyzes clinical trial data
12. Statistician reports clinical trial results to PI
13. PI reports clinical trial results to Sponsor

Postconditions/Benefits:

1. PI has reported clinical trial results to Sponsor

Extensions:

Variations:

Use Case 4.0: Carry Out Clinical Trial Activities

Primary Actor: Clinician

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

FDA—Food and Drug Administration

IRB—Institutional Review Board

PI—Principal Investigator

Stakeholders and Interests:

Patient—to receive safe and effective treatment

Principal Investigator—to answer questions of scientific interest

Clinician—to treat patients and collect the required data in compliance with the protocol

Sponsor—to fund research to answer questions of scientific interest

Data Manager—to collect the data required by the protocol

Institutional Review Board—to protect the patients and the interests of the research institution

Food and Drug Administration—to ensure that federal regulations are obeyed and patients are protected

Clinical Trial Tool Developers—to produce and market software tools that are useful in the clinical trials domain

Preconditions/Special Requirements:

1. The clinical trial has been activated.

Minimal Guarantees: The patient's health and quality of life are not unnecessarily endangered. All federal and local regulations are followed.

Success Guarantees/Performance Goals: Patient receives the treatment prescribed in the protocol. All the correct data are collected to in order to answer the questions of scientific interest.

Trigger: PI has prepared instructions for clinical trial Clinicians

Main Success Path/Workflow:

1. Clinicians enroll Patients
2. Clinicians treat Patients
3. Patients receive treatment
4. Patient provides clinical trial data.
5. Clinician collects clinical trial data
6. Clinicians prepare clinical trial reports for PI and Sponsor
7. Clinician reports adverse events to PI

Postconditions/Benefits:

1. Clinical trial protocol is approved
2. Sponsor has funded clinical trial.

Extensions:

Variations:

Use Case 5.0: Develop Case Report Forms

Primary Actor: Data Manager

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

CDE—Common Data Element

Stakeholders and Interests:

Principal Investigator—to answer questions of scientific interest

Clinician—to treat patients and collect the required data in compliance with the protocol

Sponsor—to fund research to answer questions of scientific interest

Data Manager—to collect the data required by the protocol

Statistician—to analyze the clinical trial results

CDE Reviewer—to ensure that cancer centers and groups are using CDEs appropriately

Forms Technician—to accurately render the case report forms as designed by the Data Manager

Preconditions/Special Requirements:

1. The protocol has been drafted by the PI.

Minimal Guarantees: Problems with case report form development are reported to the PI for resolution.

Success Guarantees/Performance Goals: Case report forms have been developed. Case report form items support the statistical analysis plan.

Trigger: The Data Manager receives the draft protocol from the PI.

Main Success Path/Workflow:

1. Data Manager evaluates the protocol's data collection needs
2. Statistician defines data analysis needs for the Data Manager
3. Data manager drafts case report forms for protocol
4. Data manager guides case report forms through internal approvals
5. Data Manager revises case report forms as required by internal reviews
6. Forms Technician creates finished version of case report forms
7. Data Manager reviews case report forms for final edits
8. Data Manager sends internally approved case report forms to Protocol Coordinator

Postconditions/Benefits:

1. Protocol Coordinator has internally approved case report forms for the protocol

Extensions:

Variations:

Use Case 6.0: Provide Statistical Expertise for Clinical Trial

Primary Actor: Statistician

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

CDE—Common Data Element

Stakeholders and Interests:

Principal Investigator—to answer questions of scientific interest

Data Manager—to collect the data required by the protocol

Statistician—to analyze the clinical trial results

Preconditions/Special Requirements:

1. The clinical trial concept has been prioritized by the Concept Committee.

Minimal Guarantees: Statistical design problems are reported to the PI so that they can be addressed.

Success Guarantees/Performance Goals: Appropriate statistical input has been given for the clinical trial's experimental design, accrual targets, eligibility criteria and case report form items.

Trigger: The PI asks the Statistician for help with the statistical design.

Main Success Path/Workflow:

1. Statistician reviews draft clinical trial concept
2. Statistician develops experimental design for clinical trial
3. Statistician develops analysis plan for clinical trial
4. Statistician identifies accrual needs for ancillary studies
5. Statistician determines factors to include in eligibility criteria
6. Statistician defines data analysis needs for case report forms
7. Statistician sends statistical design to PI
8. PI incorporates statistical design into protocol

Postconditions/Benefits:

1. Statistical design has been developed for the clinical trial
2. Statistical design has been incorporated into the protocol.

Extensions:

- 8.a PI requests revisions to statistical design
- 9.a Statistician revises statistical design

Variations:

Use Case 7.0: Develop Protocol Documents

Primary Actor: Protocol Coordinator

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

CDE—Common Data Element

Stakeholders and Interests:

Principal Investigator—to answer questions of scientific interest

Sponsor—to fund research to answer questions of scientific interest

Data Manager—to collect the data required by the protocol

Statistician—to analyze the clinical trial results

Institutional Review Board—to protect the patients and the interests of the research institution

Protocol Coordinator—to ensure that an acceptable, scientifically valid protocol document is developed in a reasonable period of time

CDE Reviewer—to ensure that cancer centers and groups are using CDEs appropriately

Preconditions/Special Requirements:

1. The clinical trial concept has been approved by the Sponsor.

Minimal Guarantees: Problems in protocol development will be reported to the PI for resolution. All protocols are must be approved by the Sponsor.

Success Guarantees/Performance Goals: Protocol document has been created that will enable the researchers to answer the questions of scientific interest. Protocol document has been created that meets the approval of all participants and the Sponsor.

Trigger: PI receives approval to create the protocol document.

Main Success Path/Workflow:

1. Protocol Coordinator incorporates boilerplate items into protocol document
2. Protocol Coordinator pulls sections from previous protocols for re-use
3. Protocol Coordinator incorporates new items into the protocol document
4. PI provides guidance on protocol development
5. Protocol Coordinator communicates with protocol development participants about protocol
6. Protocol Coordinator incorporates suggested changes into the protocol document
7. PI reviews and approves the final protocol document
8. PI submits the protocol to the Sponsor
9. Sponsor approves the protocol

Postconditions/Benefits:

1. Protocol has been developed.
2. Revised protocol has been approved by Sponsor.

Extensions:

- 9.a Sponsor requests revisions to protocol document
- 10.a PI revises protocol document
- 11.a Protocol Coordinator incorporates revisions into the protocol document
- 12.a PI submits revised protocol to the Sponsor

Variations:

Use Case 8.0: Develop New Common Data Elements

Primary Actor: CDE Committee

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

CDE—Common Data Element

Stakeholders and Interests:

CDE Reviewer—to ensure that cancer centers and groups are using CDEs appropriately

CDE Committee—to develop and improve a set of Common Data Elements that will serve as a accepted, computationally valid terminology for research into a particular type of cancer

CDE Support Staff—to help the CDE Committees and CDE Reviewers manage the development and improvement of Common Data Elements

Preconditions/Special Requirements:

1. NCI has determined that CDEs should be created for a specific type of cancer

Minimal Guarantees:

Success Guarantees/Performance Goals: A set of new Common Data Elements has been developed for a disease. The CDEs are linked to existing standards where possible. The set of CDEs is published so that users may access it.

Trigger: NCI assembles the CDE Committee.

Main Success Path/Workflow:

1. CDE Committee assembles resources
2. CDE Support organizes the resources
3. CDE Committee sorts through the resources
4. CDE Committee organizes data elements
5. CDE Committee reduces data elements
6. CDE Committee links data elements to existing standards
7. CDE Support organizes CDE Committee output
8. CDE Committee revises data elements
9. CDE Committee finalizes Common Data Elements
10. CDE Support manages publication of new Common Data Elements

Postconditions/Benefits:

1. A set of new CDEs has been published.

Extensions:

Variations:

Use Case 9.0: Evaluate Proposed Changes/Additions to Common Data Elements

Primary Actor: CDE Committee

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

CDE—Common Data Element

Stakeholders and Interests:

CDE Reviewer—to ensure that cancer centers and groups are using CDEs appropriately

CDE Committee—to develop and improve a set of Common Data Elements that will serve as a accepted, computationally valid terminology for research into a particular type of cancer

CDE Support Staff—to help the CDE Committees and CDE Reviewers manage the development and improvement of Common Data Elements

Preconditions/Special Requirements:

1. CDEs have been published for the type of cancer.
2. Changes to CDEs have been suggested.

Minimal Guarantees: All CDE changes must be approved by the CDE Committee.

Disapprovals of changes will be communicated back to those who proposed the changes.

Success Guarantees/Performance Goals: The updated set of CDEs is published so that users may access it.

Trigger: CDE Reviewer and CDE Support Staff send proposed CDE changes to CDE Committee.

Main Success Path/Workflow:

1. CDE Committee reviews proposed CDE changes/additions
2. CDE Support researches proposed CDE changes/additions for CDE Committee
3. CDE Committee estimates impact of proposed CDE changes/additions
4. CDE Committee approves proposed CDE changes/additions
5. CDE Support manages publication of revised Common Data Elements

Postconditions/Benefits:

1. An updated set of CDEs has been published

Extensions:

- 4.a CDE Committee rejects proposed CDE changes/additions
- 4.b CDE Committee modifies proposed CDE changes/additions

Variations:

Use Case 10.0: Validate Case Report Forms

Primary Actor: CDE Reviewer

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

CDE—Common Data Element

Stakeholders and Interests:

CDE Reviewer—to ensure that cancer centers and groups are using CDEs appropriately

CDE Committee—to develop and improve a set of Common Data Elements that will serve as a accepted, computationally valid terminology for research into a particular type of cancer

CDE Support Staff—to help the CDE Committees and CDE Reviewers manage the development and improvement of Common Data Elements

Data Manager—to collect the data required by the protocol

Preconditions/Special Requirements:

1. Data Manager has developed case report forms

Minimal Guarantees: Problems with case report forms are communicated back to Data Managers.

Success Guarantees/Performance Goals: Case report forms comply with Common Data Elements.

Trigger: Protocol and case report forms are submitted to NCI.

Main Success Path/Workflow:

1. CDE Reviewer evaluates submitted case report forms
2. CDE Reviewer verifies that submitted case report forms are CDE compliant
3. CDE Reviewer communicates review results to Data Manager
4. CDE Reviewer approves case report form
5. CDE Reviewer identifies potential additional data elements from case report forms
6. CDE Reviewer identifies potential changes to data elements from case report forms

Postconditions/Benefits:

1. Case report forms are approved for use in the clinical trial.

Extensions:

- 4.a CDE Reviewer requests revisions to case report forms
- 5.a Data Manager revises case report forms
- 6.a Data Manager submits revised case report forms

Variations:

Use Case 11.0: Approve Clinical Trials

Primary Actor: Sponsor

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

CDE—Common Data Element

Stakeholders and Interests:

Principal Investigator—to answer questions of scientific interest

Sponsor—to fund research to answer questions of scientific interest

Protocol Coordinator—to ensure that an acceptable, scientifically valid protocol document is developed in a reasonable period of time

CDE Reviewer—to ensure that cancer centers and groups are using CDEs

appropriately

Preconditions/Special Requirements:

1. Drug development has been planned.
2. Sponsor has solicited clinical trial.

Minimal Guarantees: All clinical trial submissions are thoroughly evaluated by the Sponsor. Evaluation results are returned to the PI.

Success Guarantees/Performance Goals: The Sponsor has approved the clinical trial protocol. The Sponsor may proceed with securing FDA approval for the protocol.

Trigger: PI submits letter of intent/concept/proposal

Main Success Path/Workflow:

1. Sponsor reviews letter of intent/concept/proposal
2. Sponsor approves letter of intent/concept/proposal
3. PI submits protocol to Sponsor
4. Sponsor reviews protocol
5. Sponsor approves protocol

Postconditions/Benefits:

1. Sponsor has approved the clinical trial

Extensions:

- 2.a Sponsor requests revisions to letter of intent/concept/proposal
- 3.a PI revises letter of intent/concept/proposal
- 4.a PI submits revised letter of intent/concept/proposal to Sponsor

- 2.b Sponsor disapproves letter of intent/concept/proposal

- 5.c Sponsor requests revisions to protocol
- 6.c PI revises protocol
- 7.c PI submits revised protocol to Sponsor

- 5.d Sponsor disapproves protocol

Variations:

Use Case 12.0: Evaluate Clinical Trial Results

Primary Actor: Sponsor

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

CDE—Common Data Element

Stakeholders and Interests:

Principal Investigator—to answer questions of scientific interest

Sponsor—to fund research to answer questions of scientific interest

Data Manager—to collect the data required by the protocol

Statistician—to analyze the clinical trial results

Protocol Coordinator—to ensure that an acceptable, scientifically valid protocol document is developed in a reasonable period of time

CDE Reviewer—to ensure that cancer centers and groups are using CDEs

appropriately

Preconditions/Special Requirements:

1. Clinical trial has been concluded
2. Clinical trial results have been reported

Minimal Guarantees: The Sponsor evaluates whether the clinical trial answered the questions of scientific interest.

Success Guarantees/Performance Goals: Questions of scientific interest have been answered. The answers can be incorporated into future research plans.

Trigger: PI submits clinical trial results to Sponsor

Main Success Path/Workflow:

1. Sponsor reviews clinical trial results for primary study
2. Sponsor reviews clinical trial results for ancillary studies
3. Sponsor validates that questions of scientific interest have been answered
4. Sponsor assesses impact on future drug development
5. Sponsor identifies ideas for future research

Postconditions/Benefits:

1. Impact of clinical trial results on future drug development has been assessed
2. Ideas for future research have been identified

Extensions:

- 3.a Sponsor requests that PI determine why questions of scientific interest have not been answered
- 4.a PI determines why questions of scientific interest have not been answered

Variations:

- 4' Sponsor aggregates clinical trial results with the results from other trials
- 5' Sponsor assesses impact on future drug development
- 6' Sponsor identifies ideas for future research

Use Case 13.0: Design Tools for Clinical Trials

Primary Actor: Clinical Trial Tool Developer

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

CT Developer—Clinical Trial Tool Developer

PI—Principal Investigator

Stakeholders and Interests:

Clinical Trial Tool Developers—to produce and market software tools that are useful in the clinical trials domain

Patient—to receive safe and effective treatment

Principal Investigator—to answer questions of scientific interest

Clinician—to treat patients and collect the required data in compliance with the protocol

Sponsor—to fund research to answer questions of scientific interest

Data Manager—to collect the data required by the protocol

Statistician—to analyze the clinical trial results

Protocol Coordinator—to ensure that an acceptable, scientifically valid protocol document is developed in a reasonable period of time

CDE Reviewer—to ensure that cancer centers and groups are using CDEs

appropriately

Preconditions/Special Requirements:

1. User requirements have been developed

Minimal Guarantees: The tool design is driven by the user requirements.

Success Guarantees/Performance Goals: The tool will meet user requirements. The tool will work with the available technology. The tool will work with the available data. The tool will work within the user environment.

Trigger: Clinical Trial Tool Developer has generated a set of testable user requirements

Main Success Path/Workflow:

1. CT Developer reviews the user requirements
2. CT Developer identifies available technologies
3. CT Developer identifies sources of data
4. CT Developer investigates the user environment
5. CT Developer identifies constraints
6. CT Developer conducts trade studies
7. CT Developer drafts a system architecture
8. CT Developer drafts a user interface

Postconditions/Benefits:

1. System architecture is drafted
2. User interface is drafted

Extensions:

Variations:

Use Case 14.0: Approve Clinical Trial for the Institution

Primary Actor: Institutional Review Board

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

IRB—Institutional Review Board

Stakeholders and Interests:

Patient—to receive safe and effective treatment

Principal Investigator—to answer questions of scientific interest

Sponsor—to fund research to answer questions of scientific interest

Institutional Review Board—to protect the patients and the interests of the research institution

Preconditions/Special Requirements:

1. Clinical trial protocol approved by Sponsor

Minimal Guarantees: All clinical trials are approved by the IRB before they may be conducted at the institution.

Success Guarantees/Performance Goals: The well being of the Patients is protected. The institutions interests are protected. The clinical trial is likely to answer questions of scientific interest.

Trigger: Clinical trial protocol is submitted to the IRB

Main Success Path/Workflow:

1. IRB reviews protocol document
2. IRB reviews data collection plan and case report forms
3. IRB conducts risk/benefit analysis
4. IRB approves protocol document and case report forms

Postconditions/Benefits:

1. The clinical trial may be conducted at the institution

Extensions:

- 4.a IRB requests revisions to the protocol document and case report forms
- 5.a PI revises protocol document
- 6.a PI requests case report form revision from Data Manager
- 7.a Data Manager revises case report forms
- 8.a Data Manager returns case report forms to PI
- 9.a PI submits revised protocol and case report forms to IRB

- 4.b IRB disapproves protocol document and case report forms

Variations:

Use Case 15.0: Identify Clinical Trial Concepts for Development

Primary Actor: Concept Committee

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

Stakeholders and Interests:

Principal Investigator—to answer questions of scientific interest

Concept Committee—to ensure that the group or cancer center pursues the most promising clinical trial ideas

Protocol Coordinator—to develop scientifically useful clinical trial protocols that are likely to be approved with the lowest expenditure of time and resources

Preconditions/Special Requirements:

1. Sponsor has sent out clinical trial solicitations
2. PI has developed an idea for a clinical trial.

Minimal Guarantees: All clinical trial ideas are evaluated and prioritized by the Concept Committee.

Success Guarantees/Performance Goals: The most promising clinical trial concepts are given highest priority.

Trigger: PI and Protocol Coordinator submit a concept summary to the Concept Committee

Main Success Path/Workflow:

1. Concept Committee reviews the concept summary
2. Concept Committee evaluates the concept summary against other concepts
3. Concept Committee assigns a priority to the concept

Postconditions/Benefits:

1. The concept has been assigned a priority.

Extensions:

- 2.a Concept Committee requests additional information from PI
- 3.a PI provides additional concept information to Concept Committee

Variations:

Use Case 16.0: Support Remote Data Capture for Clinical Trials

Primary Actor: Clinical Trials Support Unit

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

CTSU—Clinical Trials Support Unit

RDCMS—Remote Data Capture Management System

Stakeholders and Interests:

Clinical Trials Support Unit—to promote cross-group patient enrollment and remote data capture for clinical trials

Data Manager—to collect the data required by the protocol

CDE Reviewer—to ensure that cancer centers and groups are using CDEs appropriately

Preconditions/Special Requirements:

1. CTSU has set up RDCMS
2. CDE Reviewer has reviewed case report forms for CDE compliance

Minimal Guarantees: Case report forms are evaluated by CTSU for use in remote data capture

Success Guarantees/Performance Goals: RDCMS and Common Data Elements are consistent with each other. Case report forms are available in the RDCMS for use by Clinicians and Data Managers.

Trigger: CDE Reviewer sends reviewed case report forms to CTSU

Main Success Path/Workflow:

1. CTSU evaluates case report forms
2. CTSU renders case report forms into RDCMS
3. CTSU reconciles RDCMS with Common Data Elements

Postconditions/Benefits:

1. Clinicians and Data Managers may use RDCMS for clinical trial data collection

Extensions:

Variations:

Use Case 17.0: Analyze Study Data

Primary Actor: Statistician

Scope: Common Data Elements

Level: Business – high level

Acronyms Used:

PI—Principal Investigator

Stakeholders and Interests:

Statistician—to analyze the clinical trial results

Principal Investigator—to answer questions of scientific interest

Sponsor—to fund research to answer questions of scientific interest

Preconditions/Special Requirements:

1. Clinical trial is completed
2. All clinical trial data have been collected

Minimal Guarantees: Clinical trial results have been analyzed in a reliable, scientific manner.

Success Guarantees/Performance Goals: Data have been analyzed regarding all questions of scientific interest in the clinical trial.

Trigger: Data Manager sends final data set to Statistician

Main Success Path/Workflow:

1. Statistician validates the collected data
2. Statistician performs data analysis
3. Statistician draws conclusions
4. Statistician reports clinical trial results to Principal Investigator

Postconditions/Benefits:

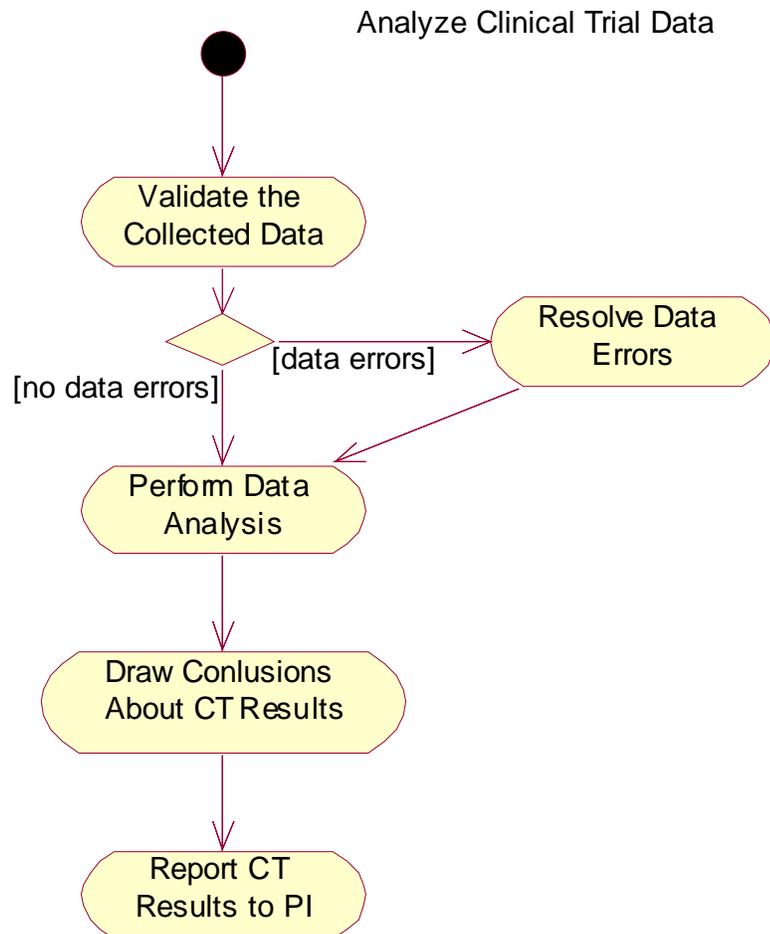
1. Clinical trial results have been obtained

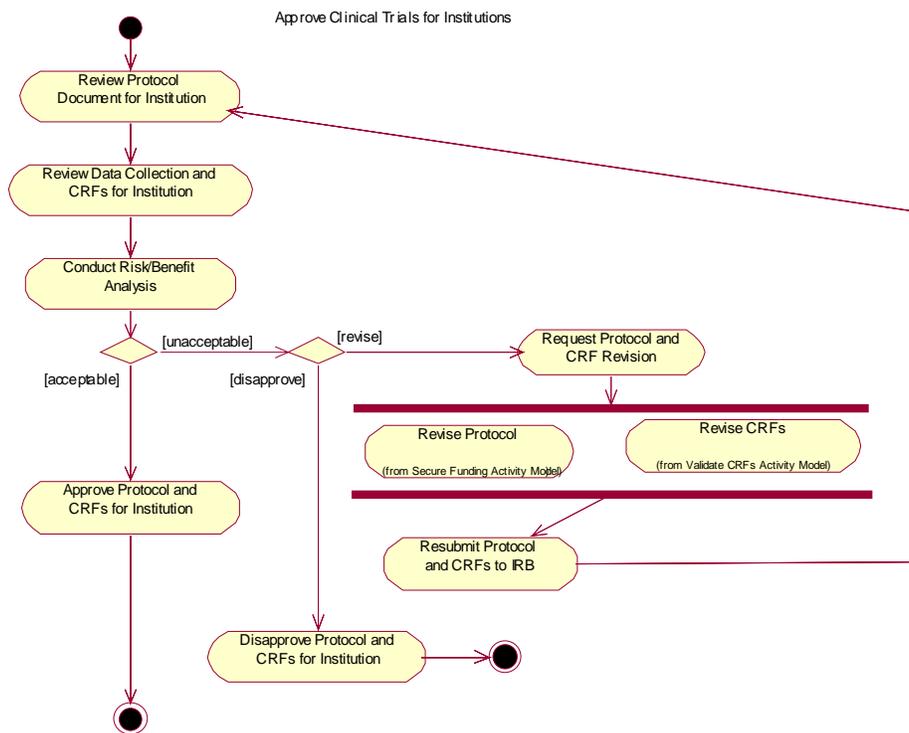
Extensions:

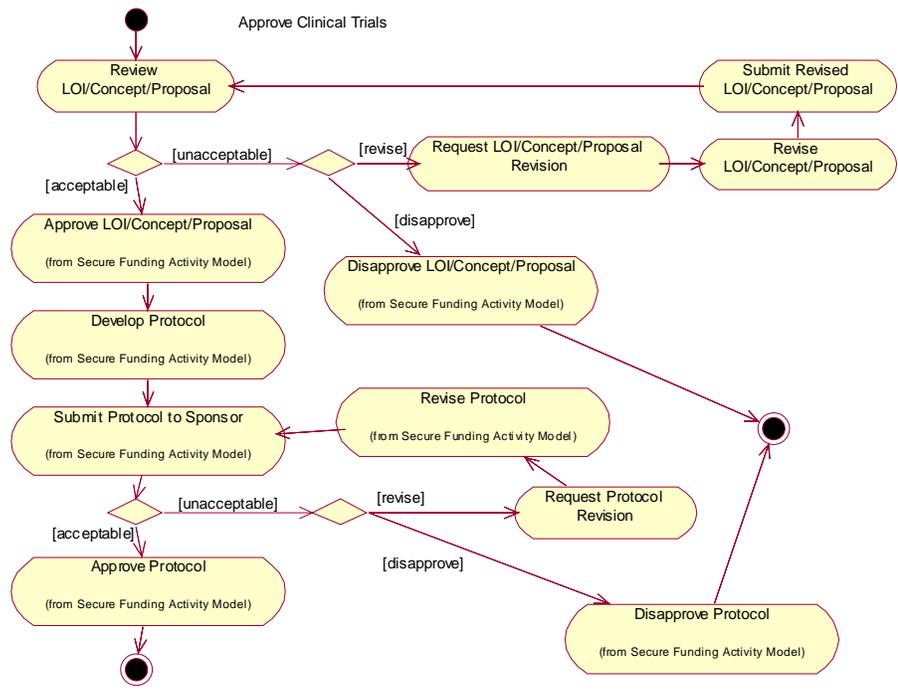
- 2.a Statistician resolves any data errors

Variations:

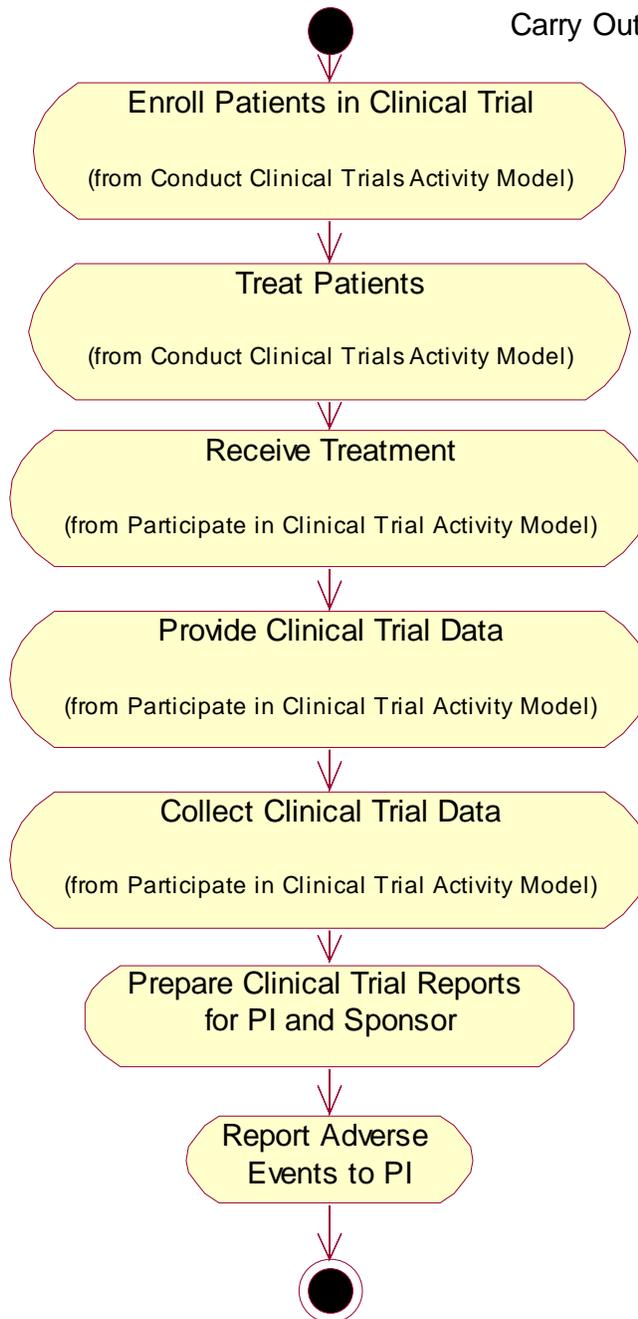
Business Use Case Activity Diagrams

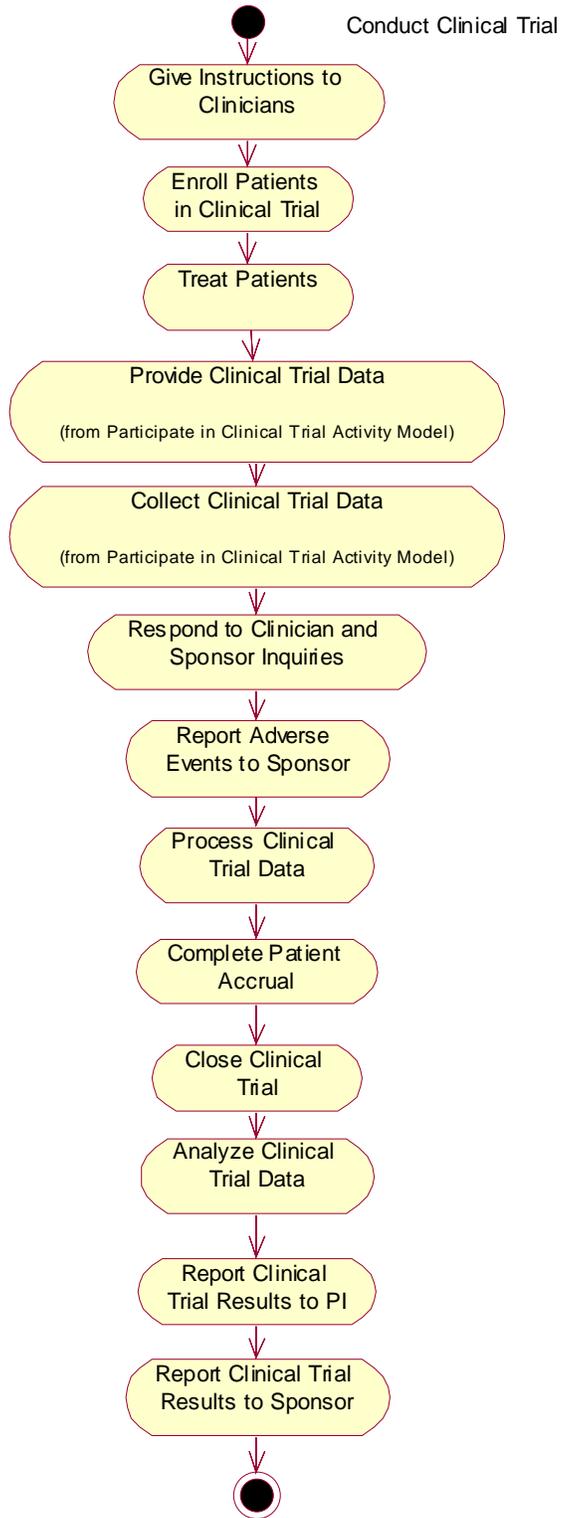




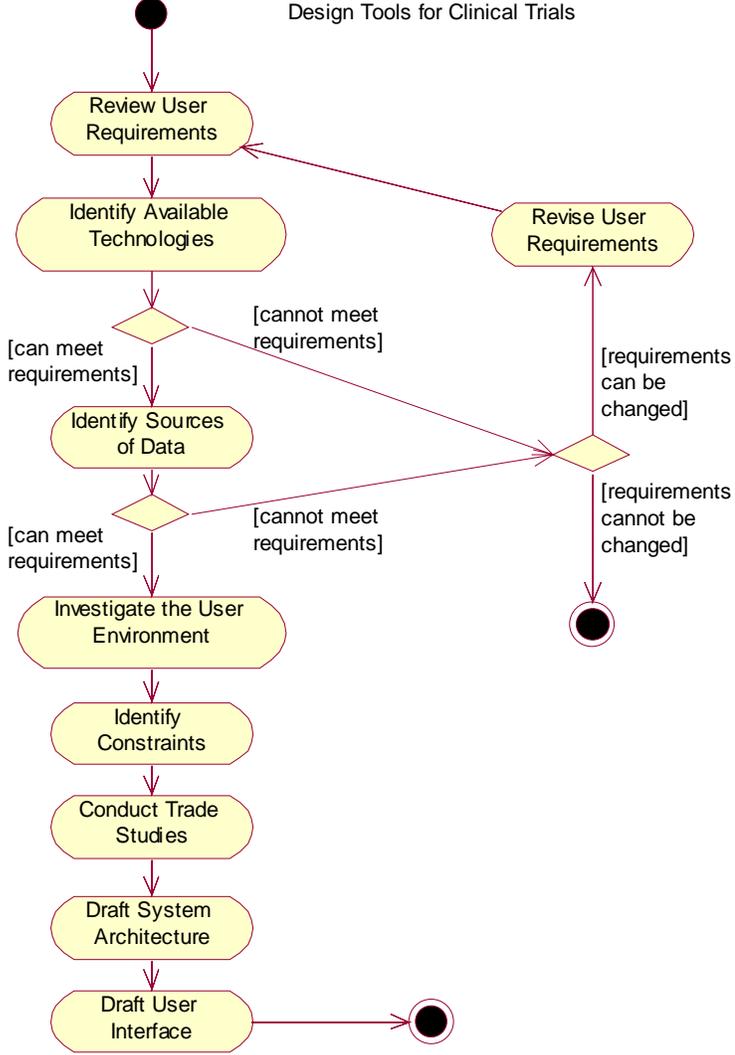


Carry Out Clinical Trial Activities

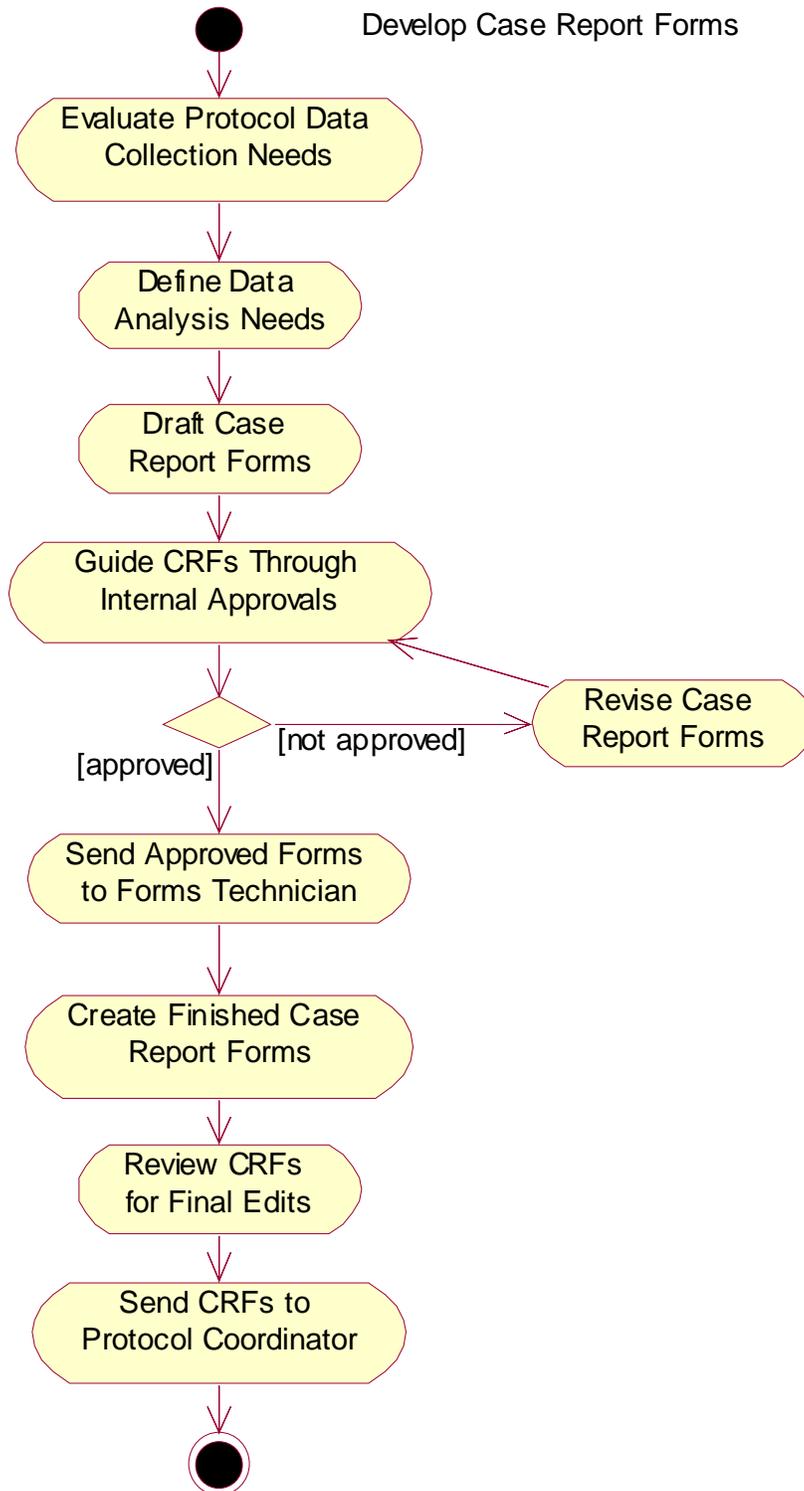




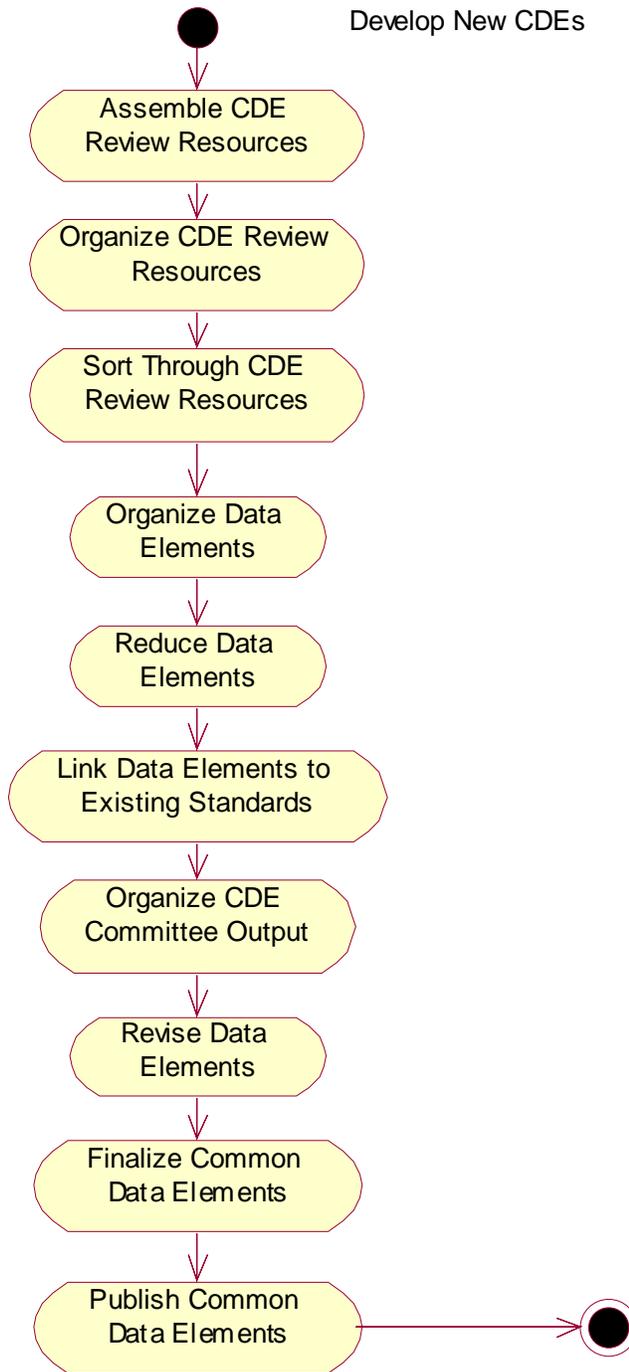
Design Tools for Clinical Trials



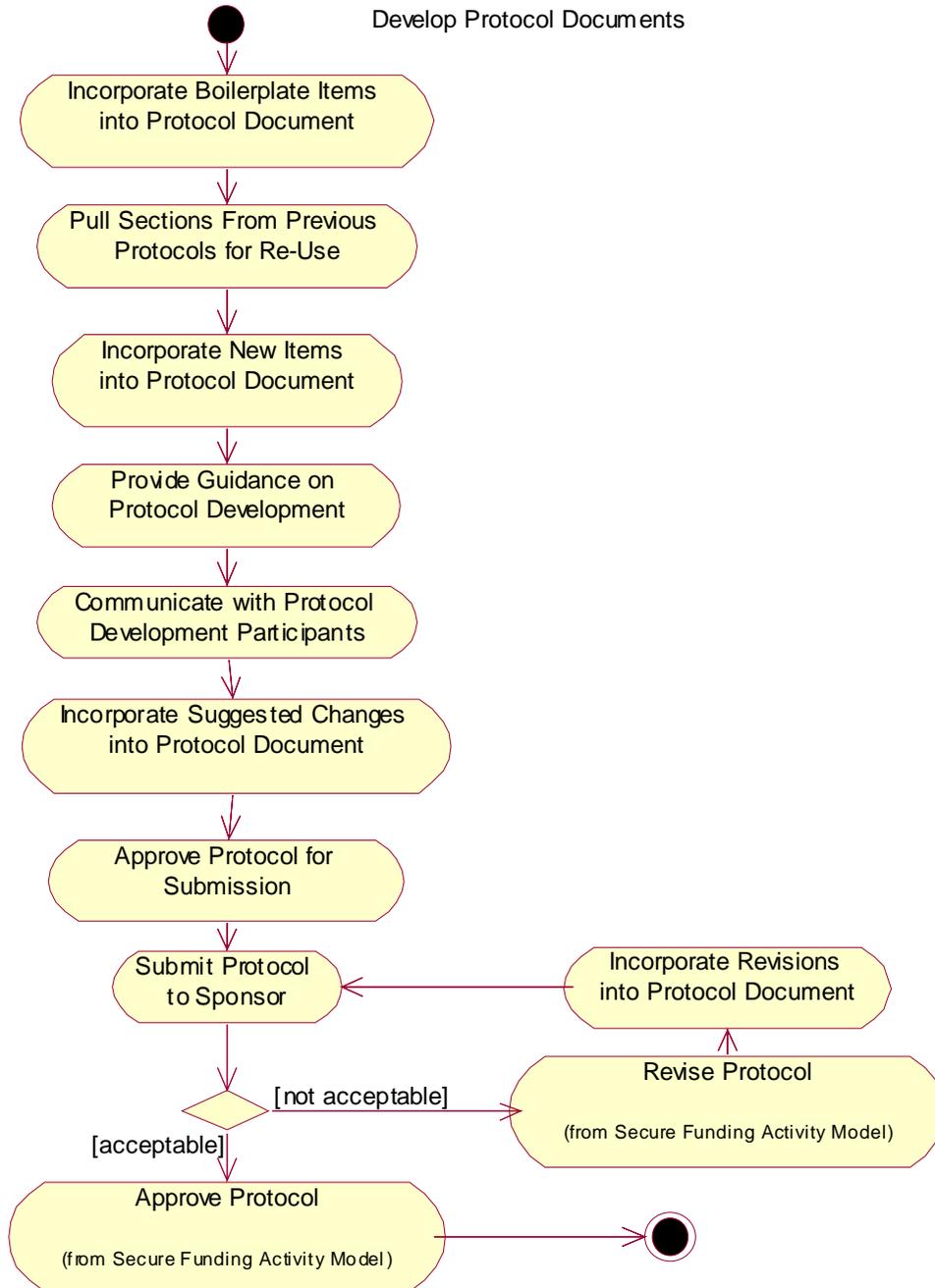
Develop Case Report Forms



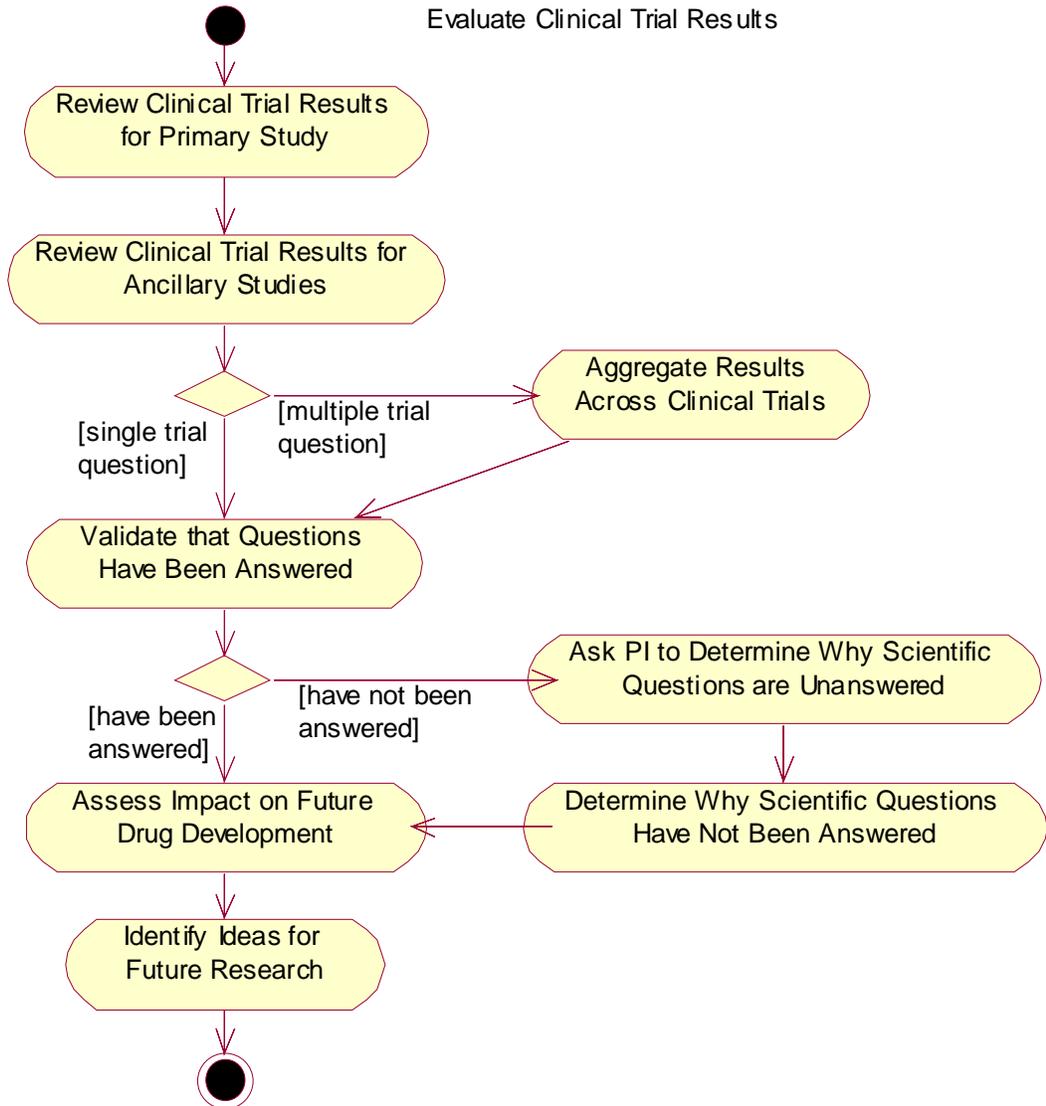
Develop New CDEs

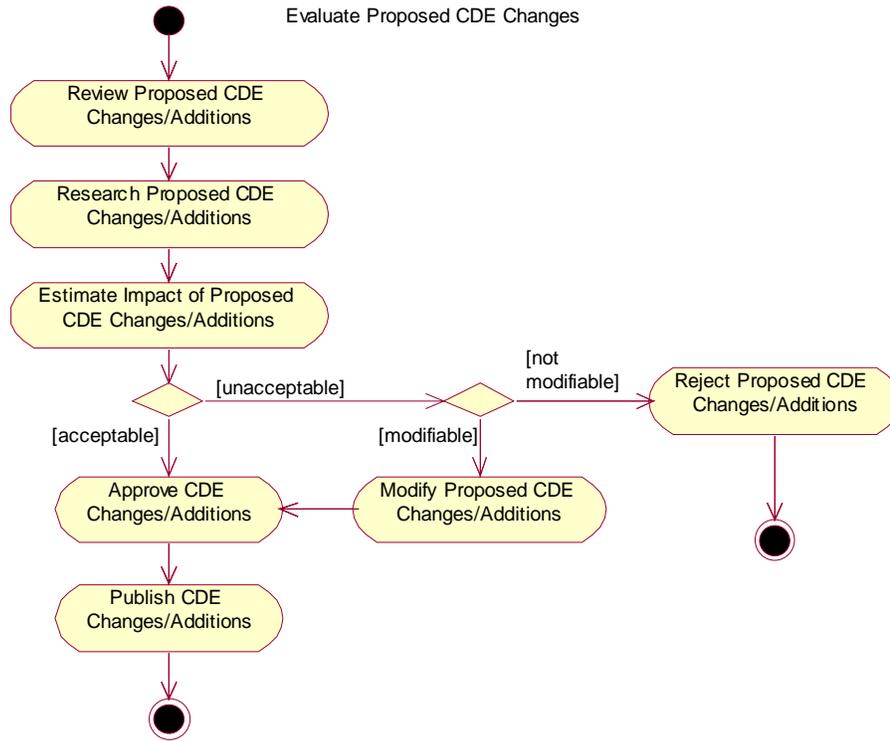


Develop Protocol Documents

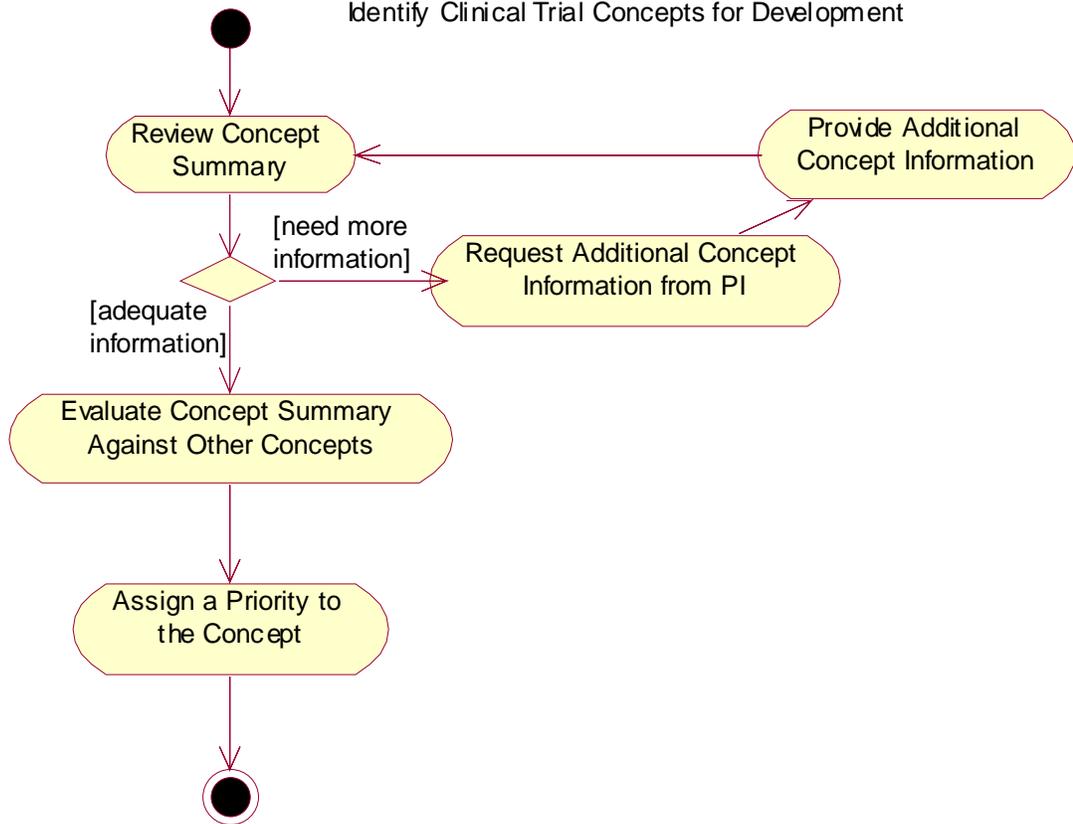


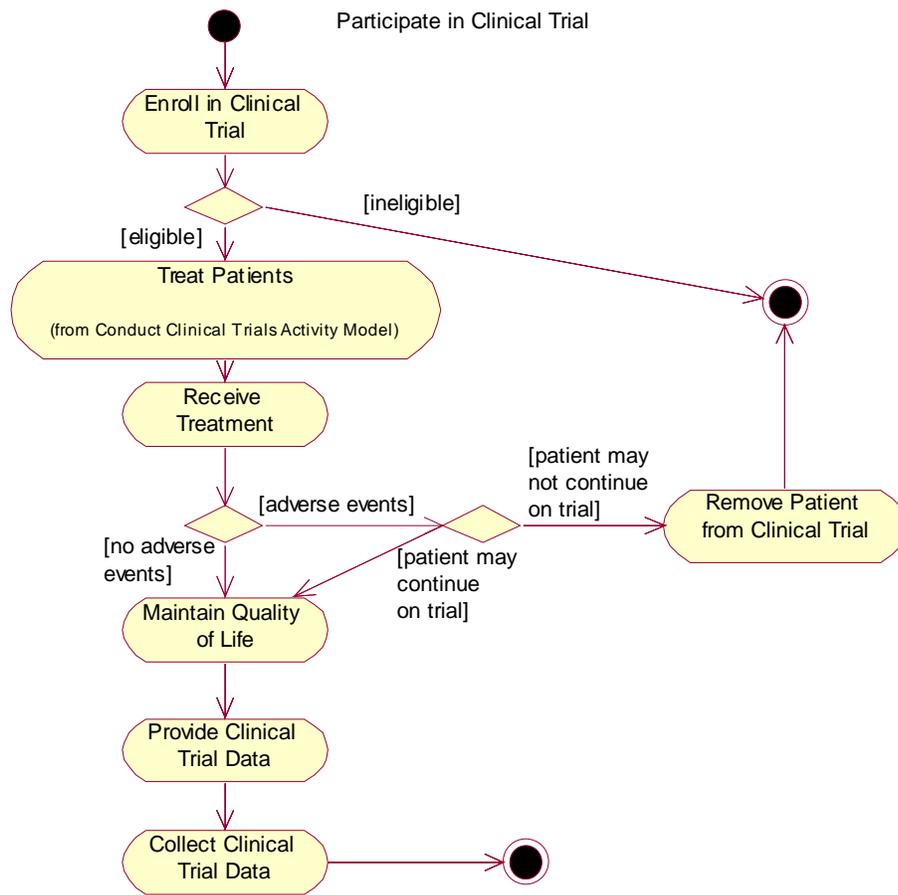
Evaluate Clinical Trial Results



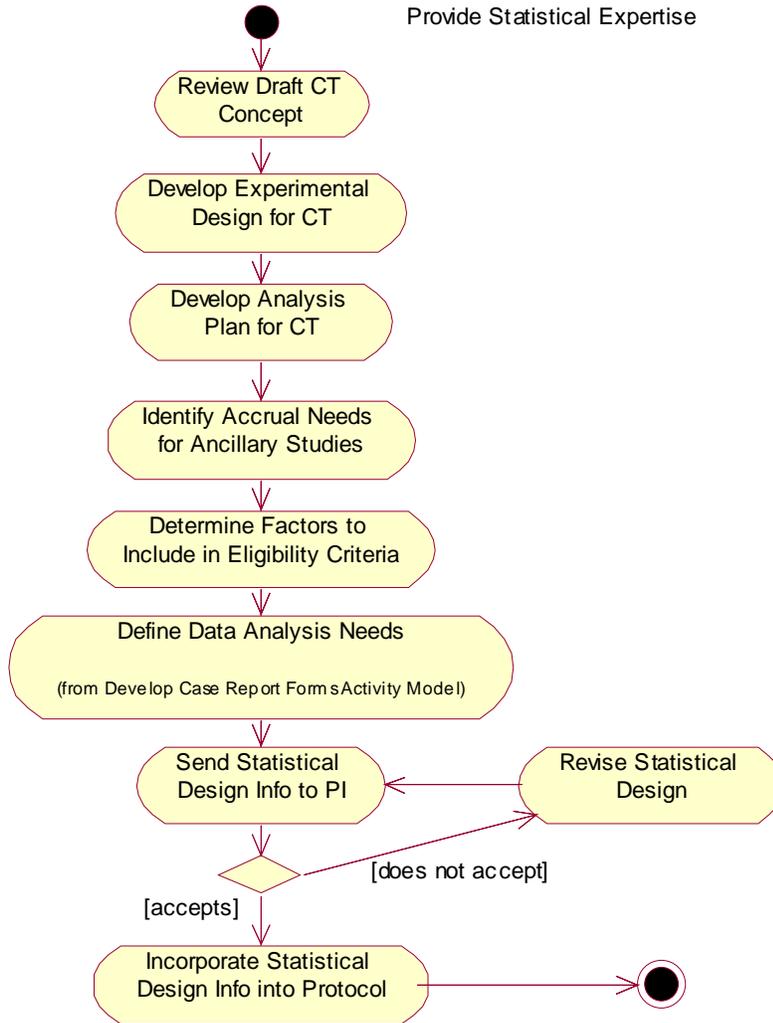


Identify Clinical Trial Concepts for Development

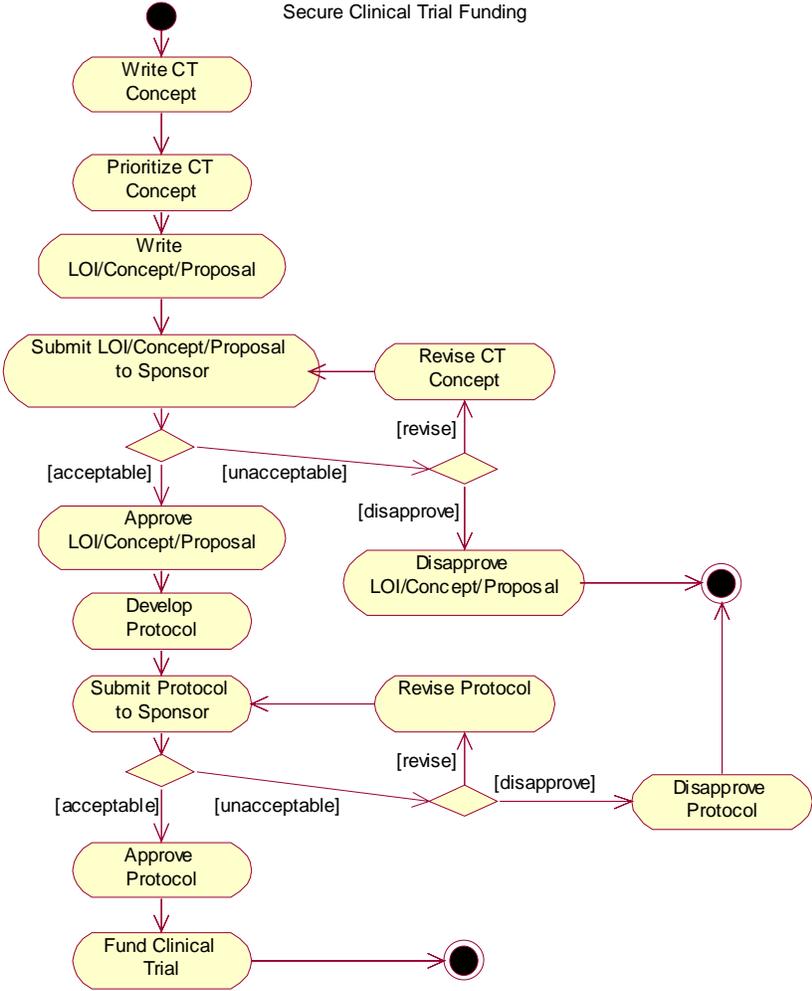




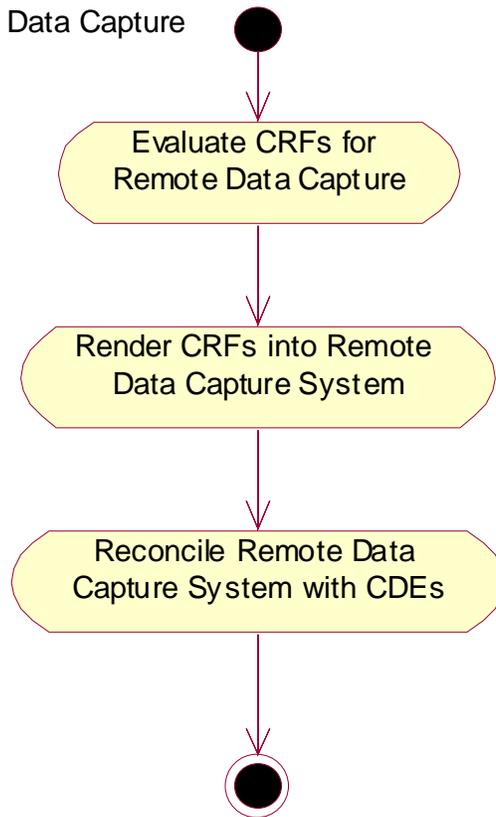
Provide Statistical Expertise



Secure Clinical Trial Funding



Support Remote Data Capture



Validate CRFs

