

1.Responsibilities of CDM

Study Setup

- CRF design and development (paper/e-CRF)
- Database build and testing
- Edit Checks preparation and testing

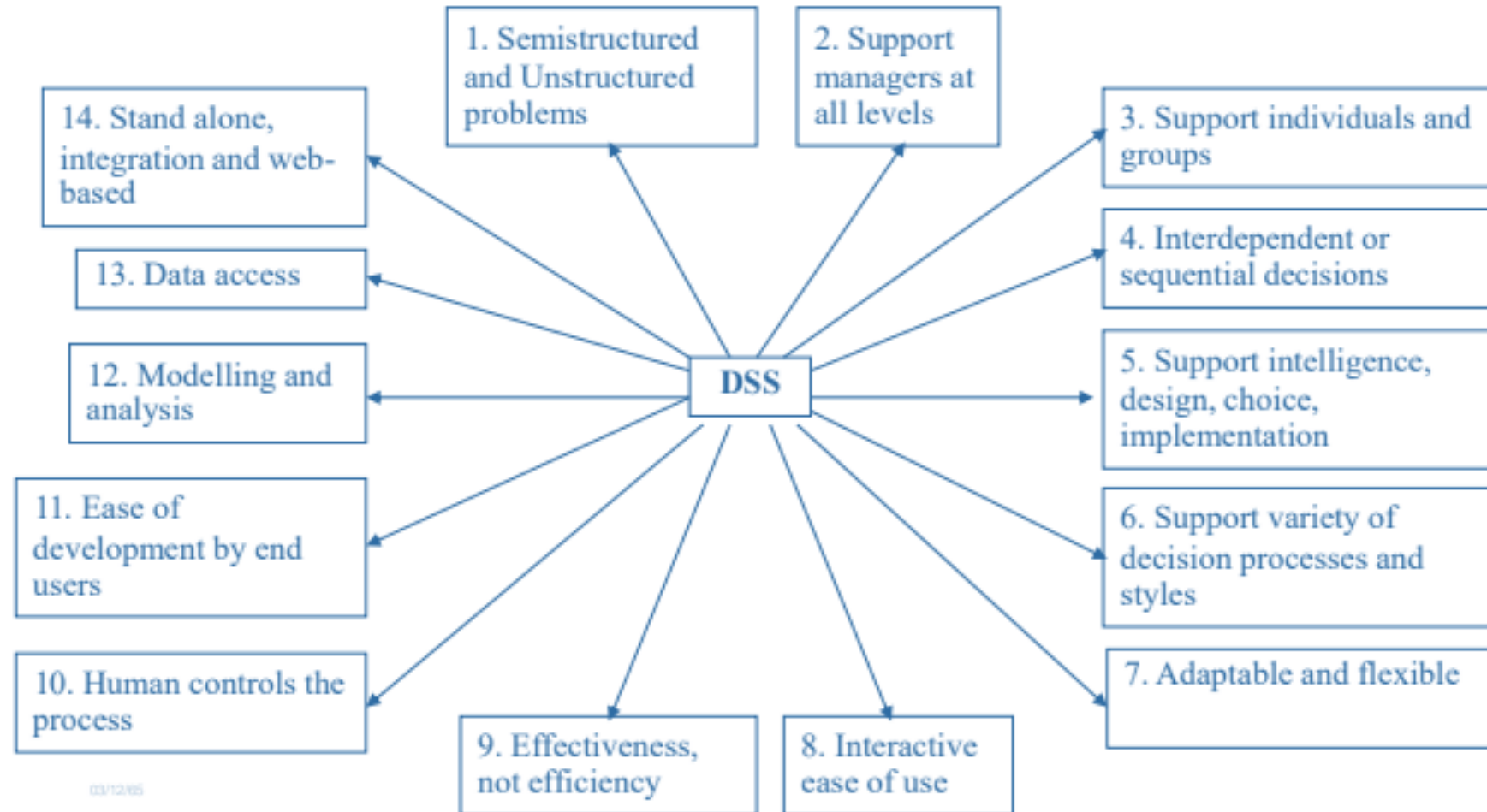
Study Conduct

- Data Entry
- Discrepancy Management
- Data Coding (using MedDRA and WHODDE dictionaries)
- Data review (Ongoing QC)
- Serious Adverse Event (SAE) Reconciliation
- Data Transfer

Study Closeout

- SAE Reconciliation
- Quality Control
- Database Lock
- Electronic Archival
- Database Transfer

2.Key characteristics and capabilities of DSS



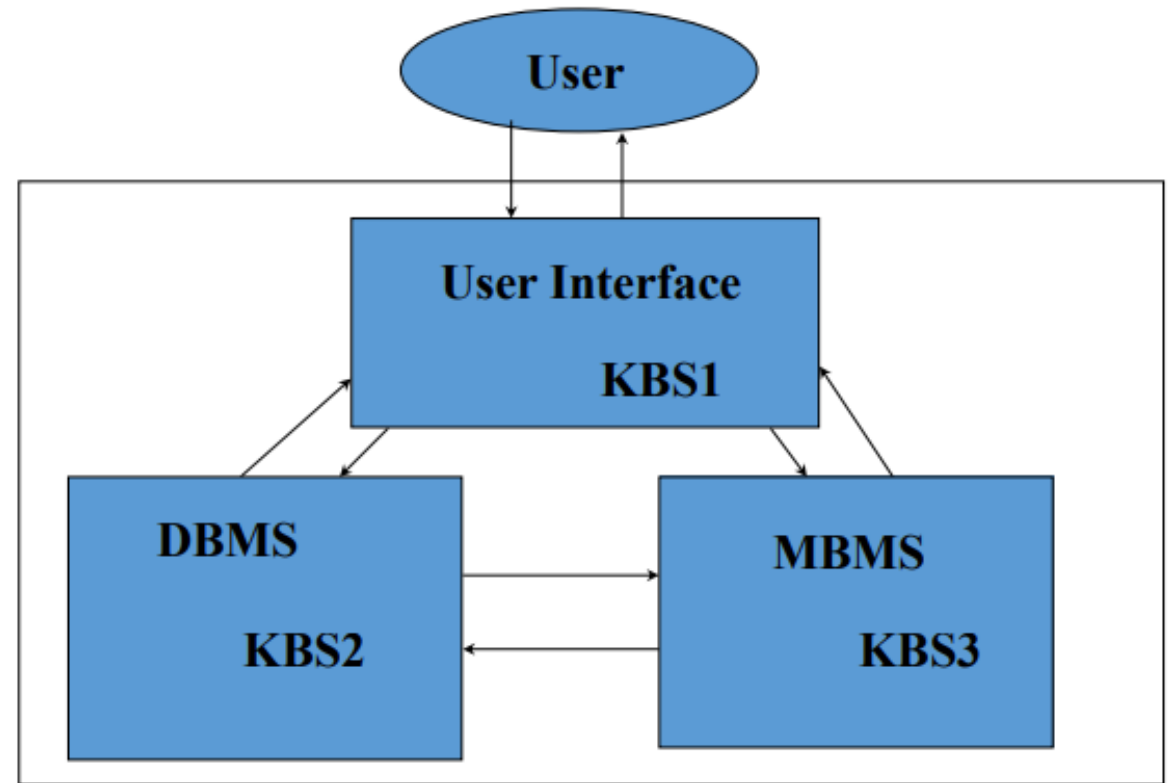
2. Characteristics and Capabilities of DSS

1. Provide support in semi-structured and unstructured situations, includes human judgment and computerized information
2. Support for various managerial levels
3. Support to individuals and groups
4. Support to interdependent and/or sequential decisions
5. Support all phases of the decision-making process
6. Support a variety of decision-making processes and styles
7. Are adaptive

8. Have user friendly interfaces
 9. Goal: improve effectiveness of decision making
 10. The decision maker controls the decision-making process
 11. End-users can build simple systems
 12. Utilizes models for analysis
 13. Provides access to a variety of data sources, formats, and types
- Decision makers can make better, more consistent decisions in a timely manner

3. DSS Components

1. Data Management Subsystem
2. Model Management Subsystem
3. Knowledge-based (Management) Subsystem
4. User Interface Subsystem
5. The User



4. Analytics: The Three types

✓ Descriptive Analytics: Classic BI

- Quantitative Assessment of Past Business Results
- Statistics, Exploratory Data Analysis, Visualization

✓ Predictive Analytics

- Quantitative Methods to Predict New Outcomes
- Forecasting, Prediction, Classification, Association

✓ Prescriptive Analytics

- Quantitative Methods to Make Better Decisions
- Decision Trees, Monte Carlo Simulation, Optimization

5. Process of Decision Making

1. Define the problem (i.e., a decision situation that may deal with some difficulty or with and opportunity).

2. Construct a model that describes the real-world problem.

3. Identify possible solutions to the modeled problem and evaluate the solutions.

4. Compare, choose, and recommend a potential solution to the problem.

6. Model types

1. Data processing model

Shows how data is processed at different stages

2. Composition model

Shows how entities are composed of other entities

3. Architectural model

Shows principal sub-systems

4. Classification model

Shows how entities have common characteristics

5. Stimulus/response model

Shows the system's reaction to events.