
بسم الله الرحمن الرحیم
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Planning a Registry

Planning a Registry

When planning a registry, it is desirable to follow these initial steps:

(1) Articulate the purpose of the registry;

(2) Determine if a registry is an appropriate means to achieve the purpose;

(3) Identify key stakeholders;

(4) Assess the feasibility of a registry;

(5) Registry team;

(6) Define the scope and rigor needed;

(7) Define the data set, patient outcomes, and target population;

(8) Develop a study plan or protocol;

(9) Develop a project plan.

Planning a Registry

1- Articulate the Registry's Purpose

- One of the first steps in planning a registry is articulating its purpose.
- A clearly defined purpose helps clarify the need for certain data.
- A registry may have a singular purpose or several purposes.
- Response to key or driving questions for determining the registry purpose

Planning a Registry

- **Key or driving questions**

1. What is the natural course of a disease in different geographic locations?
2. Are there disparities in the delivery of care?
3. Does a treatment lead to long-term benefits or harm, including delayed complications?
4. How successful is a “comprehensive” childhood immunization program?
5. How is disease progression affected by available therapies?
6. What is the safety profile of a specific therapy?
7. Is a specific product or therapy teratogenic?
8. How do clinical practices vary when treating a specific disease?
9. What characteristics or practices enhance compliance and adherence?
10. Do quality improvement programs affect patient outcomes, and, if so, how?
11. What are significant predictors of poor outcomes?
12. What clinical outcomes should be measured to improve quality of patient care?
13. Should a particular procedure or product be a covered benefit in a particular population?

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2- Determine if a Registry Is an Appropriate Means To Achieve the Purpose

Every registry developer should consider the following questions early in the planning process:

- ❖Do these data already exist?
- ❖If so, are they of sufficient quality to answer the research question?
- ❖Are they accessible, or does an entirely new data collection effort need to be initiated?

For example, could the necessary data be extracted from electronic medical records or administrative health insurance claims data?

In such cases, registries might avoid re-collecting data that have already been collected elsewhere and are accessible.

Planning a Registry

3- Identify Key Stakeholders

Typically, there are primary and secondary stakeholders for any registry.

- A primary stakeholder is usually responsible for creating and funding the registry.

The party that requires the data, such as a regulatory authority, may also be considered a primary stakeholder.

- A secondary stakeholder is a party that would benefit from knowledge of the data or that would be impacted by the results but is not critical to establishing the registry.

Treating clinicians and their patients could be considered secondary stakeholders.

Planning a Registry

4- Assess Feasibility

Planning a Registry

5- Build a Registry Team

Several different kinds of knowledge, expertise, and skills are needed to plan and implement a registry.

- The different kinds of expertise and experience that are useful include the following:
  - *Project management*
  - *Registry science*
  - *Clinical experts*
  - *Data collection and database management*
  - *Legal issues/patient privacy*
  - *Quality assurance*

Planning a Registry

6- Consider the Scope of data

- Scope of Data
  - Size
  - Duration
  - Setting
  - Geography

Planning a Registry

7- Define the Core Data Set, Patient Outcomes, and Target Population

- Core Data Set
- Patient Outcomes
- Target Population

The target population is the population to which the findings of the registry are meant to apply.

It must be defined for two basic reasons:

- First, the target population serves as the foundation for planning the registry.
- Second, it also represents a major constituency that will be impacted by the results of the registry.

Planning a Registry

8- Develop a Study Plan or Protocol

❑At a minimum, the study plan should include the registry objectives, the eligibility criteria for participants, and the data collection procedures.

❑ Ideally, a full study protocol will be developed to document the objectives, design, participant inclusion/exclusion criteria, outcomes of interest, data to be collected, data collection procedures, governance procedures, and plans for complying with ethical obligations and protecting patient privacy.

Planning a Registry

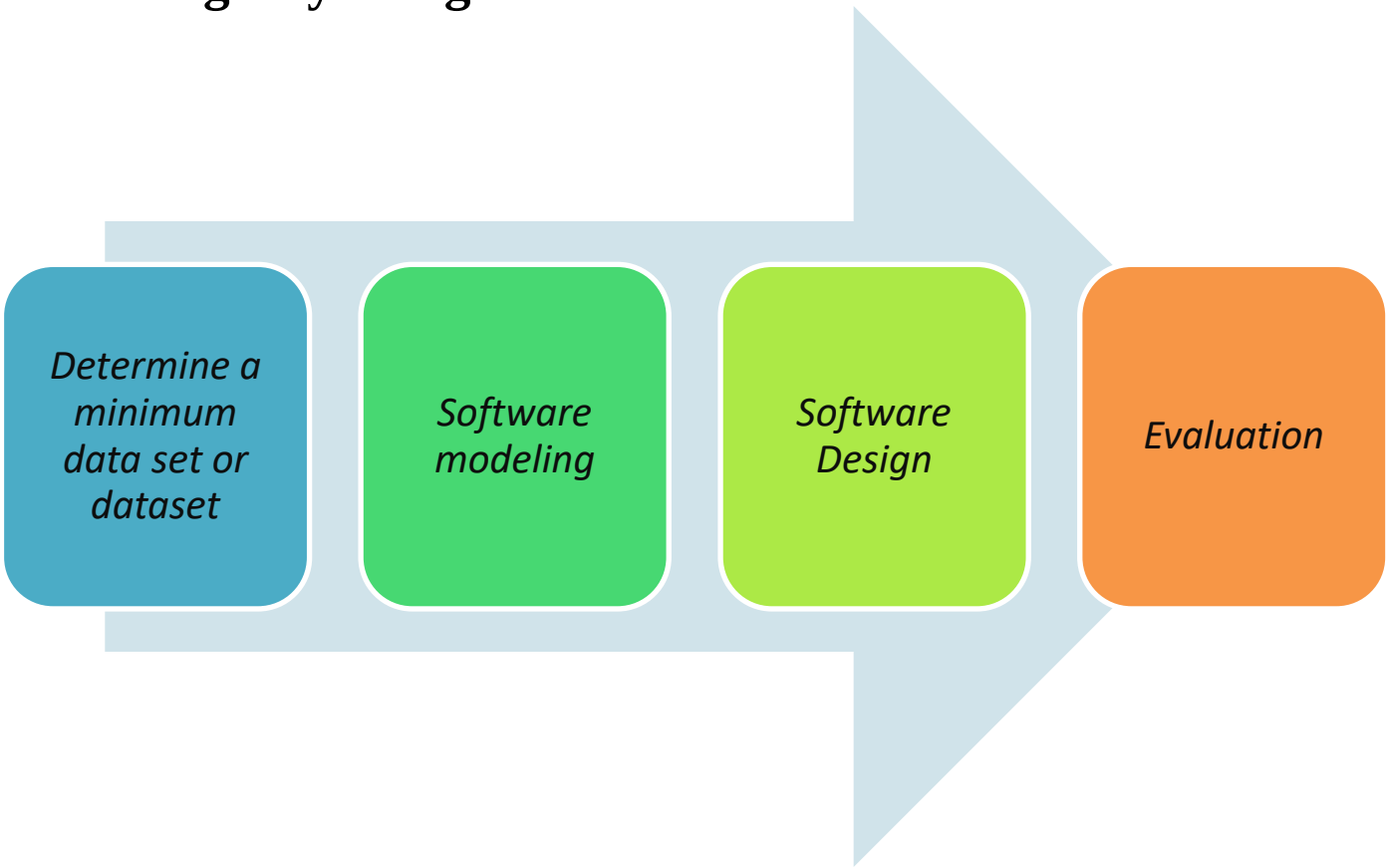
9- Develop a Project Plan

- ❖Detailed timeline
- ❖Cost management
- ❖Quality management
- ❖Staffing management
- ❖Risk management

Registry Design

Registry Design

Phases of Registry Design



Registry Design

1- Determine a minimum data set or data set

2- Software modeling

3- Software Design

4- Evaluation

Registry Design

Registry Design

1- Determine a minimum data set or dataset

2- Software modeling

3- Software Design

4- Evaluation

Unified modeling language

- *The unified modeling language (UML) is a general-purpose modeling language that is intended to provide a standard way to visualize the design of a system.*

Registry Design

Software modeling

Unified modeling language

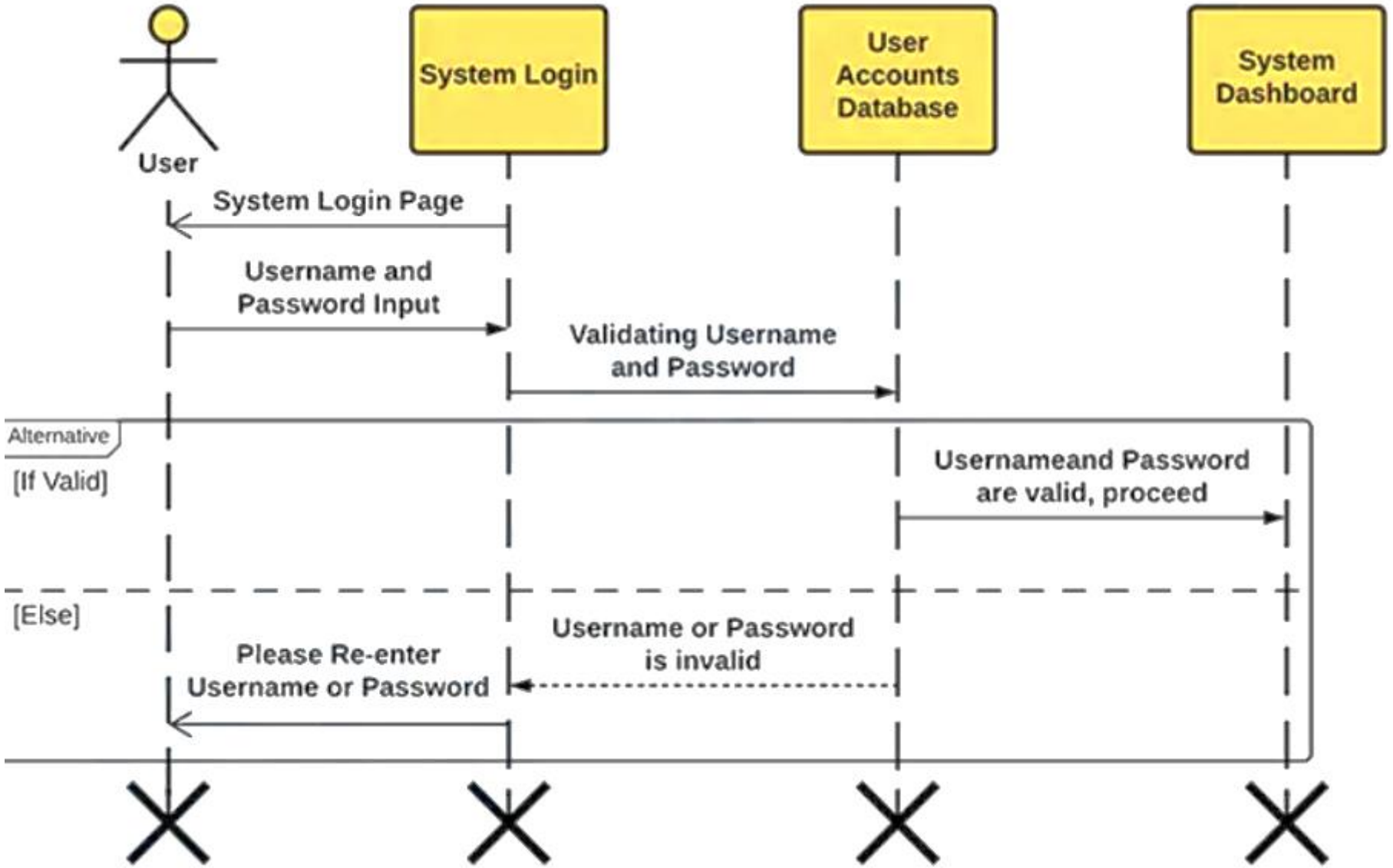
- *The main aim of UML is to **define a standard way to visualize the way a system has been designed.***
- *UML is not a programming language, it is rather a visual language.*
- *We use UML diagrams to portray the behavior and structure of a system .*

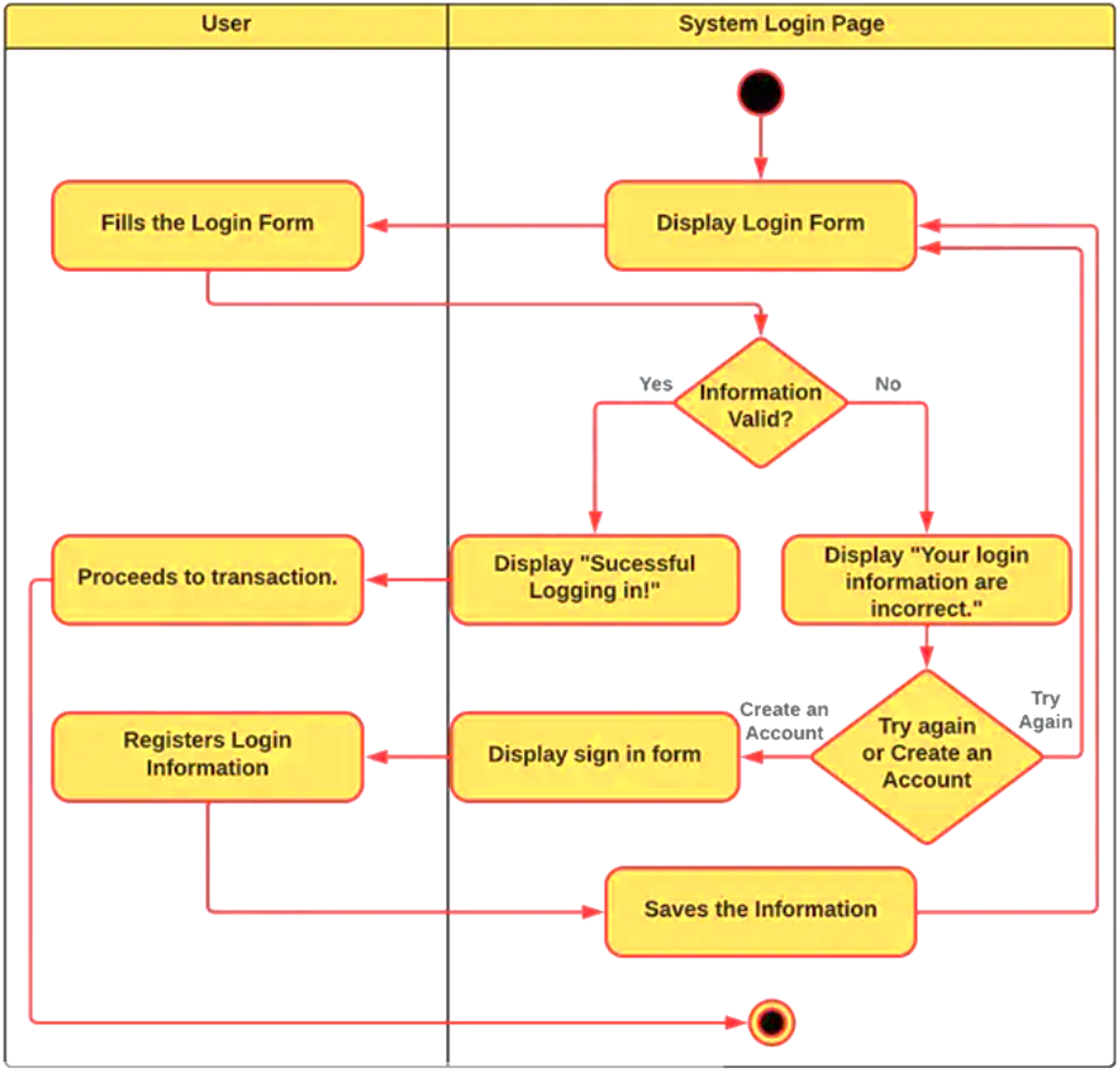
Registry Design

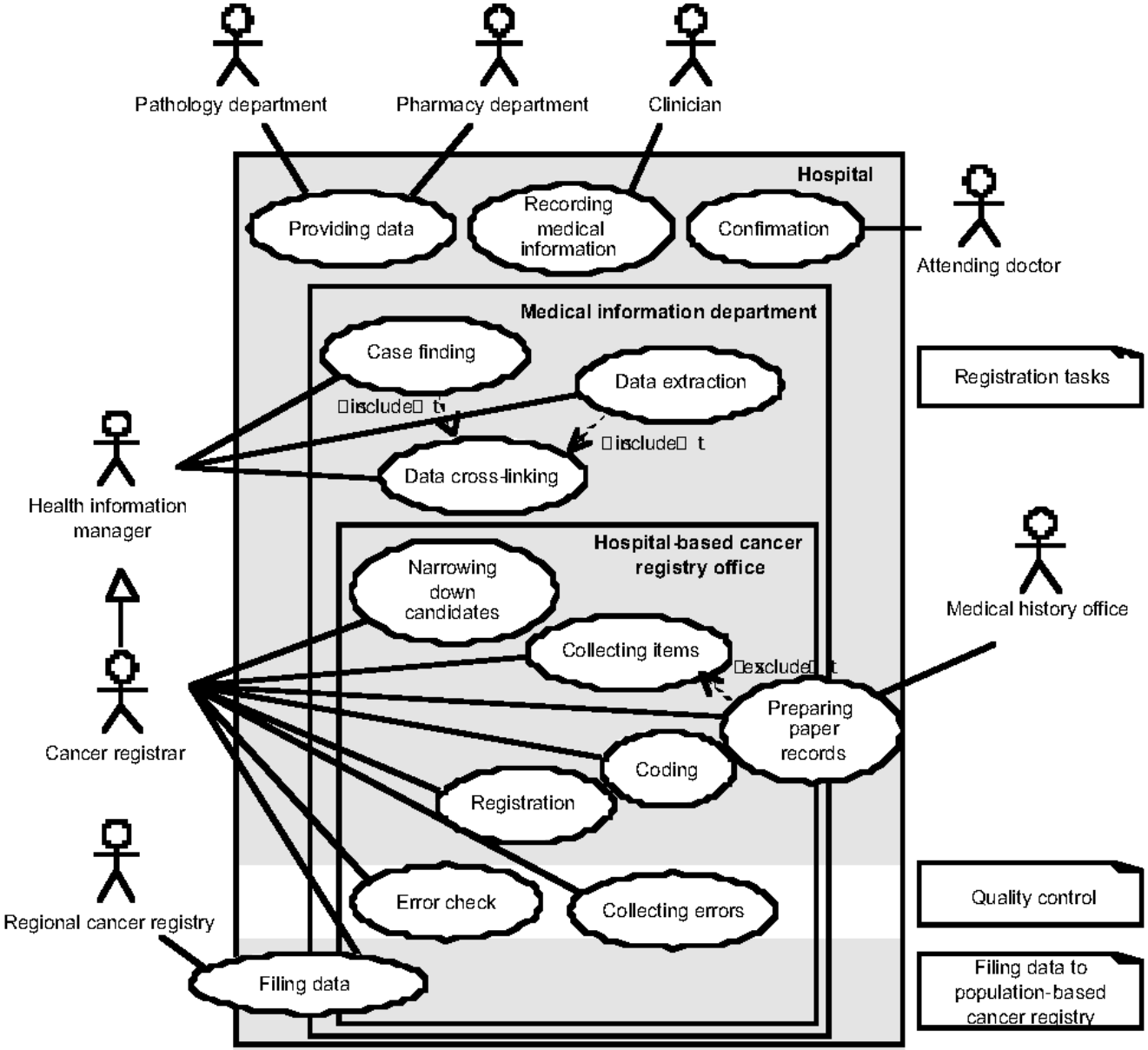
Software modeling

1. *Unified modeling language*

- ❖ **Structural Diagrams –** Capture static aspects or structure of a system.
- ✓ Structural Diagrams include: Component Diagrams, Object Diagrams, Class Diagrams and Deployment Diagrams.
- ❖ **Behavior Diagrams –** Capture dynamic aspects or behavior of the system.
- ✓ Behavior diagrams include: Use Case Diagrams, State Diagrams, Activity Diagrams and Interaction Diagrams.


User
System Login
User Accounts Database
System Dashboard
System Login Page
Username and Password Input
Validating Username and Password
Alternative
[If Valid]
Usernameand Password are valid, proceed
[Else]
Username or Password is invalid
Please Re-enter Username or Password


User
System Login Page
Fills the Login Form
Display Login Form
Yes
Information Valid?
No
Proceeds to transaction.
Display "Sucessful Logging in!"
Display "Your login information are incorrect."
Registers Login Information
Create an Account
Display sign in form
Try again or Create an Account
Try Again
Saves the Information


Pathology department
Pharmacy department
Clinician
Hospital
Providing data
Recording medical information
Confirmation
Attending doctor
Medical information department
Case finding
Data extraction
Registration tasks
Health information manager
Data cross-linking
Hospital-based cancer registry office
Narrowing down candidates
Medical history office
Collecting items
Cancer registrar
Preparing paper records
Coding
Registration
Regional cancer registry
Error check
Collecting errors
Quality control
Filing data
Filing data to population-based cancer registry

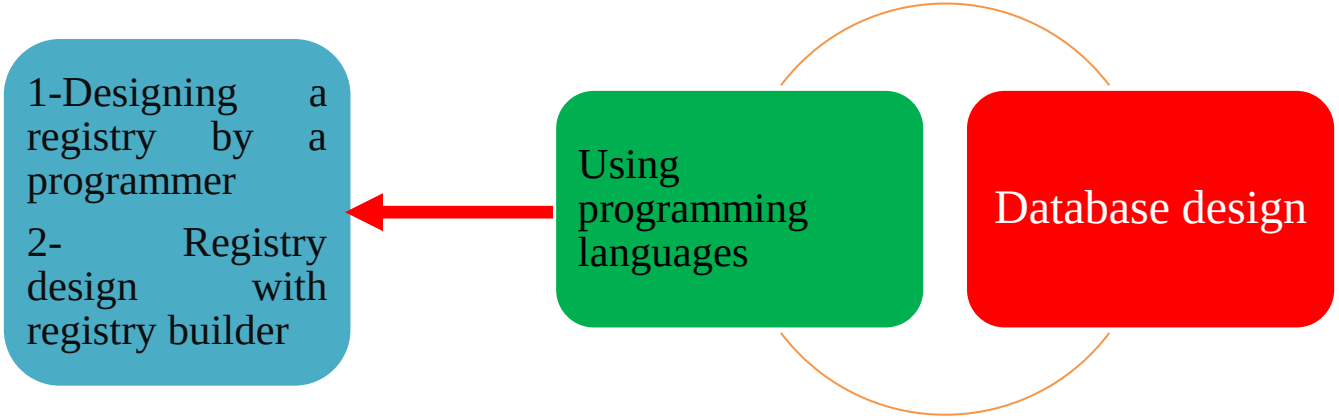
Registry Design

1- Determine a minimum data set or dataset

2- Software modeling

*3- **Software Design***

4- Evaluation



Registry Design

1- Determine a minimum data set or dataset

2- Software modeling

3- Software Design

4- Evaluation

- ***Usability evaluation***

  Usability Evaluation focuses on how well users can learn and use a product to achieve their goals.

  Example?

- ***Usability evaluation methods***

  1- Usability Inspection Methods

  2- Usability Testing with Users


Manual Testing more suited for Testing Types
Functional Testing
Unit Testing
Exploatory Testing
Ad-Hoc Testing
Integration Testing
UAT [User Acceptance Testing]
Usability Testing
Alpha Testing
Beta Testing
Compliance Testing

Pilot Testing

Pilot Testing

- Pilot testing is software testing where a user verifies the software before their final deployment or launch.
- The most common form of pilot testing is to continuously test the entire software so that its weak areas can be detected.

Objectives of Pilot Testing

- The main objective of this testing is to evaluate the cost, project performance, feasibility, time, and risk.
- The objective of pilot testing is also to find out the end-user's response to the software.
- To explore the possibilities of software success before launch.

Barriers and facilitators for registry systems

Barriers for registry systems

Management problems

- **Budgetary and financial shortages and constraints**
- **Lack of manpower and human resources**
- **Not being clear about the implementation of registries has a higher priority**
- **Lack of governance of the organization on which the registry is implemented**
- **Lack of a precise protocol for implementing and executing these systems**
- **Continuous changing of managers**

Facilitators

- ***Management facilitators***

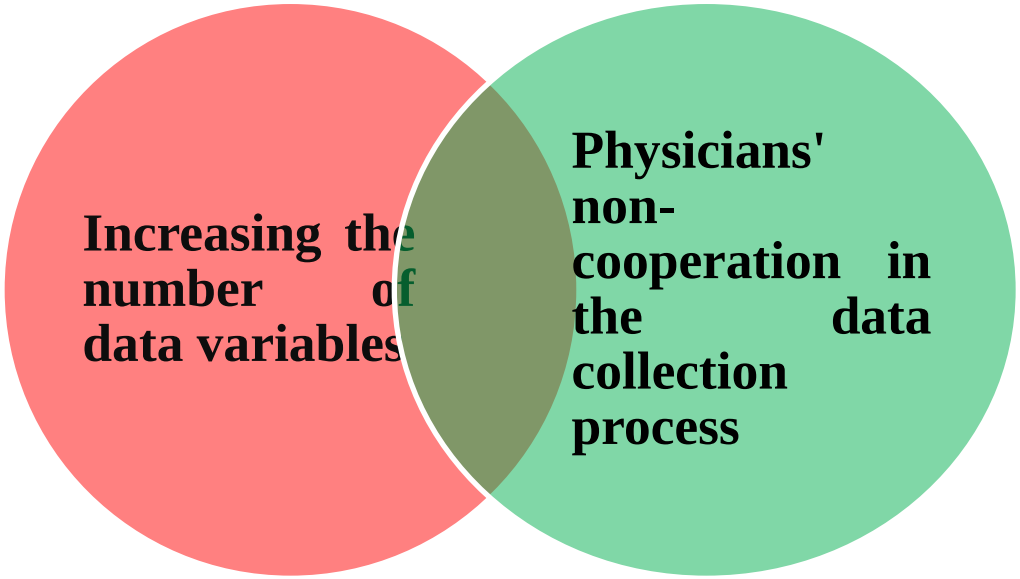
✓ Finance the registry system

✓ Introduction of important and common diseases by the Ministry of Health

✓ Developing appropriate guidelines result in the consistent implementation of registry systems in different centers

Barriers for registry systems

Data collection-related problems



Facilitators

- ***Data collection-related facilitators***

✓ Appropriate data set (minimum data set)

✓ Collecting registry data from electronic health record system

✓ Hiring appropriate data collectors

Barriers for registry systems

Technological problems

- ✓ Lack of technology support
- ✓ Restrictions on the data exchange between registry systems and other information systems
- ✓ Internet disruption and its low speed internet
- ✓ Non-use of user-friendly software in registries

Facilitators

- ***Technological facilitators***

✓ Data exchanges between registries and other systems

✓ Provision of user-friendly software

✓ Internet bandwidth usage

Barriers for registry systems

Poor cooperation/coordination between stakeholders

- ✓ Lack of coordination and cooperation of different stakeholders
- ✓ Lack of coordination between universities

Facilitators

- ***Poor cooperation/coordination between stakeholders facilitators***

✓ Increasing compromise and agreement

✓ Creating a registry working group in each university

Barriers for registry systems

Threats to ethics, data security and confidentiality

- ✓ Data confidentiality issues
- ✓ Lack of transparency of data ownership
- ✓ Non-backup of data stored in registry systems

Facilitators

- ***Threats to ethics, data security and confidentiality facilitators***

✓ Formulating appropriate rules for data access

✓ Providing patients’ information to researchers without a name and a phone number and address

✓ Limiting data loggers' access to data

✓ Cloud competing and server mirroring

Barriers for registry systems

Lack of motivation and interest

- ✓ Mandatory entry of data into the registry system by staff while on duty
- ✓ Increasing employee workload through the registry functions
- ✓ Lack or limitation of financial incentives
- ✓ The concern of physicians about the transparency of their performance through the registration of their patients' data

Facilitators

- ***Lack of motivation and interest facilitators***

✓ Monetary or non-monetary incentives

https://research.behdasht.gov.ir/Reg%E2%81%84reg

وضعیت سیستمهای ثبت در دانشگاه علوم پزشکی کرمان

با تشکر از حسن توجه شما