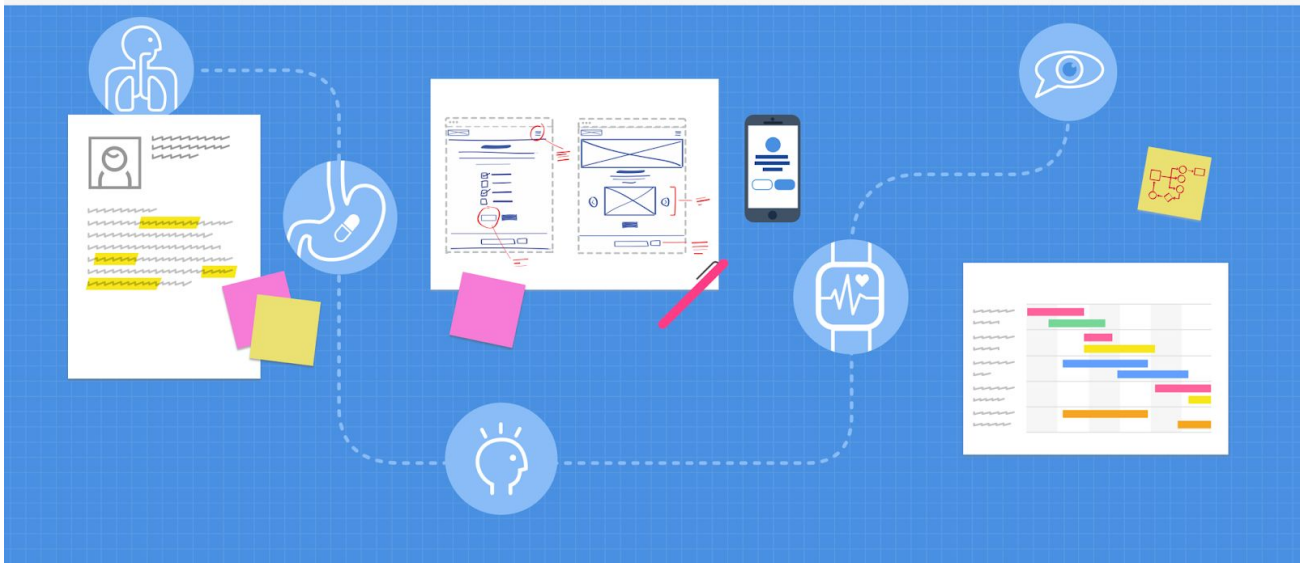


# User-centred design and development for healthcare



## Design Development Plan Template Version 1.0

# Design Development Plan Template

## 1. Project Overview

*This is an overarching description of the project.*

*Provide information regarding the following:*

- Overall initial objective of the project,
- Project phases
- Team members (roles, responsibilities, training, qualifications, timelines and dependencies gantt chart)
- Confidentiality
- Confirmation of understanding - confirm if it is necessary for confirmation of team member's understanding of the project
- Geographical considerations for location or data sharing.

## 2. Use and Target Markets

*Provide information regarding the determined use and target markets for the project deliverable.*

## 3. Project Plan

*Define the planning approach of the project, this should include:*

- Project monitoring time frame used
- Responsible person for identifying dependencies, milestones and governance dates

## 4. Roles and Responsibilities

*Define the roles and responsibilities of team members on the project.*

*Ensure that all responsibilities relating to project management responsibilities are stated, such as, data integrity & risk register management.*

## 5. Supplier Agreements and Subcontracts

*List the suppliers and subcontractors engaged on the project.*

## 6. Deliverables

*Provide details regarding the deliverables of the project. This can be presented in a table with details of the deliverable, the project phase, specific date, additional useful details for the deliverable and who is responsible for delivery.*

## 7. Study Management

Define the approach for the management of the study.

If this is listed in other documents or elsewhere you can state as such instead of replicating information, otherwise, provide details of how the study will be managed (be sure to include who will manage the process and any external collaborators.)

## 8. Risk Management

Define the risk management plan.

Include the following information:

- Purpose of the plan
- Roles and responsibilities
- Risk capture and mitigation - Risk Template
- Adverse Events or incident reporting and management.

## 9. Software Development

Define plan for software development, if software development is not needed please state as such and provide any reasons, if pertinent. This should include:

- Roles and responsibilities,
- Processes and tools used
- Version control of deliverables,
- Issue detection and reporting
- Risk management
- Timelines & dependencies.

### a. Design Verification

Define plan for design verification, this should include:

- Verification testing scope & strategies
- Required resources and activities
- Roles and responsibilities
- Test release plan
- Deliverables
- Timeline

### b. Design Validation

Define plan for design validation, this should include

- Validation testing scope and strategies
- Required resources and activities
- Roles and responsibilities
- Test release plan

- Risk management
- Deliverables
- Timeline

## 10. Design Reviews

Define the plan for design reviews, if a design review is not needed in this project, please state as such. This should include:

- Roles and responsibilities,
- Review agenda
- Deliverable
- Frequency

## 11. Data Management

Define how the data will be managed, this should include:

- The type of data used in the project
- Data storage
- Accessibility
- Risk management and incident reporting

### a. Data integrity

A subsection of Data Management. This should describe how the data integrity will be maintained through the data lifecycle.

## 12. Issue Resolution and Change Control

Define the process for raising issues for resolution and the change control approach to be used.

## 13. Data Retention

Define the approach to data retention, this should include:

- Retention timelines
- Archiving process
- Information security

## 14. Document Control

Define how document control will be managed, this should include:

- *Roles and responsibilities (specifying sign-off responsibilities)*
- *Version control process*

## 15. Analysis

*Define the approach to the analysis, whether statistical or quantitative, also mention if no analysis will be undertaken.*

## 16. Client Communication

*Define how the project progress will be communicated to the client, this should include:*

- *The medium used*
- *The format used in the medium, for example, a spreadsheet or simple written update*
- *The point person for client communication*
- *What is to be communicated*
- *When communication is made, for example, weekly with project report and or in the event of an incident*