Health IT Developer Guidelines

Scope

These guidelines are a set of recommendations for all software applications in the health and care sector. They can be used as a guidance document for those implementing new software systems or as a checklist for existing systems. Typically, this document serves health manager profiles with useful information when setting the scope of a (new) healthcare IT application, but it can also be a first-to-read reference document before starting your work as a developer.

Health applications in this document are defined in the largest meaning possible to all electronic software systems destined to healthcare users (citizens, patients or their informal caregivers) or healthcare professionals (doctors, nurses, care and paramedic staff) being: electronic health records (EHR), cloud applications, clinical decision support applications, mobile health apps, native apps, web applications, wearables + their software, etc.

Towards this variety of health applications (apps), the Flemish Government wants to set a long-term strategy and quality control that directly influences in the long-term success of these applications and their adoption. We therefor recommend you follow guidelines below as a roadmap towards successful user engagement and retention. They will guide you through your development and integration pathway and can serve as a check if you took each requirement into account. Make sure that you test your application before publishing/releasing to the public and ensure they function well on the devices and operating systems you claim they do. The guidelines will also serve as a point of reference for later assessment procedures, if applicable.

Documentation overview

Privacy

- By Design / By Default
- Intended Purpose
- Informed Consent
- Data Policy
- Secondary Use

Security

- Architecture
- Authentication
- Access Control
- Personal Identifiable Information
- Data Storage 1
- Software Development Lifecycle (SDLC)

Interoperability

- Specification
- Error Handling
- Data Mapping
- Testing
- Support

Product Quality

- Quality Management System (QMS)
- Project Management
- Configuration management
- Requirements Management
- Risk Management
- Design and implementation
- Verification and Validation
- Product Release
- Maintenance and Change Management

Usability

- User Involvement and Feedback
- Ease of Use
- Support and Connectivity
- Vitalink - Usability

Accessibility

- Navigation
- Types of Content
- Forms
- Layout

Patient Safety

- Disclaimer
- CE Marking
  - Software as a medical device
  - Intended Use and Clinical Claims
  - Classification
  - General Safety and Performance Requirements (GSPR)
  - Harmonized Standards
  - Technical File (TF)
  - Labelling
  - Post Market Surveillance
- Evidence
- Alerts and Phone Calls

Examples

Bibliography

Regulation and standards

Annexes

External Links