IVDR best practices in a BioIT context

The below text assumes an ISO15189 accredited lab setting

Based on a pragmatic analysis of clinical need and patient population size, labs can prioritise which clinical tests to implement first following the framework below. This is a collaborative effort with the web-lab, clinical scientists and clinicians.

Practical framework for implementation

1. Clinical needs analysis

Analyse patient population and need for testing/screening. This results in a list of clinical requirements:
- What is the intended use of the test? What are the objectives? What are we looking for?
- Expected outcomes for the patient care
- How many patients can we reach with the test?
- What is the desired turn-around time?
- Expected time to roll-out?

2. Market study
- What are the already available products on the market?
- Evaluation of the input matrix:
  - Sample type (blood, FFPE, extracted DNA/RNA, …)
- Do they meet the clinical needs?
- And what is their CE-IVDR status?

If there is a product that meets those requirements it should be prioritised for use. If not proceed with a lab developed test. Assess the risk of the lab developed test.

3. Translate the clinical requirements to the functional/technical units that need to be implemented to satisfy them.

Document the lifecycle of the software development (V-cycle / Agile / DevOps / …), usually this entails following aspects:

Architectural design

Describe the requirements in the institutional context.
- Computer infrastructure
- Organisational framework (Data handling, workflow system)

Detailed design

In depth description of your workflow tools / dependencies
Risk analysis of the different design aspects to prepare proper implementation and verification

4. Implementation and testing

First implementation is started based on the established design (step 3):
- Document the process: code reviews, version history, release schedule, logs, …
- Organise and document the training for personnel
- Verify the functionality: testing at different levels (document your test results):
  - Process-level testing: test that every step in your workflow functions as expected
  - Functional testing: run a full analysis test, based on a chosen set of test cases
  - Integration testing: an analysis of the test in the production environment with real data
  - When available benchmark against established standards

Maintenance & Improvement
- Collect bug reports, suggestions for new functionality
- Prioritise potential changes
- Implement changes:
  - Document (link to bug reports, suggestions, security updates, …)
  - Testing
- Inform the users of significant changes on release

5. Validation

In collaboration with the web-lab, clinical scientists and clinicians, perform an analytical and clinical validation if appropriate.