Performance Evaluation Report (IVDD)

The Performance Evaluation Report contains the methods and results regarding scientific validity, analytical performance and clinical performance.

> There's a separate standard available for that: EN 13612:2002. It's very short and doesn't contain a whole lot of information. Additionally, there are three IMDRF guidance documents:
>
> - GHTF/SG5/N6:2012
> - GHTF/SG5/N7:2012
> - GHTF/SG5/N8:2012

Product

- Name: *<product name>*
- Version: *<product version>*
- Basic UDI-DI: *<insert UDI-DI, if/when available>*

Mapping of Requirements to Document Sections

EN 13612:2002 Section	Document	Section
3.1 Responsibilities and Resources	Performance Evaluation Plan	
3.2 Documentation	Performance Evaluation Plan	
3.3 Final Assessment and Review	Performance Evaluation Report (this one)	10
4.1 Preconditions	Performance Evaluation Report (this one)	7, 8, 9
4.2 Evaluation Plan	Performance Evaluation Plan	
4.3 Sites and Resources	Performance Evaluation Plan	
4.4 Basic Design Information	Performance Evaluation Plan	
4.5 Experimental Design	Performance Evaluation Plan	
4.6 Performance Study Records	Performance Evaluation Plan	
4.7 Observations and Unexpected Outcomes	Performance Evaluation Plan	
4.8 Evaluation Report	Performance Evaluation Report (this one)	(all)
5. Modifications During the Performance Evaluation Study	Performance Evaluation Plan	

EN 13612:2002 Section	Document	Section
6. Re-evaluation	Performance Evaluation Plan	
7. Protection and Safety of Probands	Performance Evaluation Plan	

1. List of Abbreviations

Abbreviation	Explanation
IVD MD	In-vitro diagnostic medical device

2. Product

- Name: *<product name>*
- Version: *<product version>*
- Basic UDI-DI: *<insert UDI-DI, if/when available>*
- UMDNS-Code:
- GMDN-Code:

3. Relevant Documents

- SOP Performance Evaluation
- Performance Evaluation Plan

4. Intended Use

Copy-paste the intended use of your device here.

5. Risk Analysis

Copy-paste the summary of your Risk Analysis Report here.

6. Medical Context and State of the Art

6.1 Medical Context

Summarize in which medical context your IVD is used. If it's an HIV test, it may be used for screening, or maybe only for people who think they've recently gotten infected with HIV.

6.2 State of the Art

Describe how this is currently done. Continuing the example above: What happens currently to those patients who are screened for HIV,

or those who think they've gotten infected? Are there any specific tests out there or is the state-of-the-art procedure another one, like (random example) doing a chest x-ray?

7. Scientific Validity

This is generally based on literature research. Whatever your IVD is measuring, the current scientific knowledge has some sort of (valid) reason for this, because it is associated with some sort of condition. Can you still follow?

Here's an example: You've developed an HIV test. Based on current scientific knowledge, it makes sense to do HIV tests on people because it's established that HIV is a non-benign disease which will lead to AIDS some time in the future. Early detection is useful because early treatment leads to favourable outcomes. Therefore, it's scientifically valid to do HIV tests.

7.1 Scientific Validity: Literature Search Methods

Describe your methods for your literature research for scientific validity. You'll probably have a list of keywords which you'll be entering in certain databases (or other literature sources).

Some example literature sources from guidance document GHTF/SG5/N7:2012:

- Scientific databases – bibliographic (e.g., MEDLINE, EMBASE);
- Specialized databases (e.g., MEDION);
- Systematic review databases (e.g., Cochrane Collaboration);
- Clinical trial registers (e.g., CENTRAL, NIH);
- Adverse event report databases (e.g., MAUDE, IRIS);
- Scientific databases – bibliographic (e.g., MEDLINE, EMBASE);
- Specialized databases (e.g., MEDION);
- Systematic review databases (e.g., Cochrane Collaboration);
- Clinical trial registers (e.g., CENTRAL, NIH);
- Adverse event report databases (e.g., MAUDE, IRIS);
- Reference texts

7.2 Scientific Validity: Literature Search Results

Describe your search results from your literature research

Database	Search term	# Hits	# Evaluated Abstracts	# Potential Relevant Publications

Database	Title	Author	Year	Summary	Relevant?	Why?

7.3 Scientific Validity: Literature Search Conclusion

This is a bit like the "discussion" section in a scientific paper. You reach some sort of conclusion, based on your literature search. In the HIV test example, this would be something like "testing for HIV is useful because HIV is the disease which subsequently leads to AIDS, and early detection of that is good".

8. Analytical Performance

Pretty simple. Describe the metrics by which your IVD detects whatever it should detect.

In the HIV test example, those could be sensitivity / specificity values, in other words: If I use this test on 100 blood samples from different patients, what sort of analytical performance can I expect?

This will require you to run your test on some sort of test set and do some analysis of those results.

8.1 Analytical Performance: Methods

Describe your methods. If you have a Machine Learning model, you could describe your test set and why you chose that specific dataset as a test set. You could also describe the metrics by which you evaluate the performance of your ML model.

8.2 Analytical Performance: Results

Describe your results. Again, similar to a peer-reviewed paper.

9. Clinical Performance

Slightly harder to comprehend and a bit similar to Scientific Validity. These are the performance metrics of your product in its intended patient population.

So, for the HIV test: You'll have some numbers for the analytical performance, but that's only on the "reagent" level. What are the

metrics when you actually use that test on real people? There's probably a different sensitivity / specificity. Maybe certain comorbidities (like other viral diseases) may lead to false-positive test results. So, this is like analytical performance, but in the real world, on real patients.

You can also do a literature research for this, or do a clinical performance study.

9.1 Clinical Performance: Methods

Describe the methods of your clinical performance evaluation.

9.2 Clinical Performance: Results

Describe your results.

10. Conclusion

Conclude why your IVD is safe and effective to use. It makes sense to refer to your intended use, the risks in your risk analysis, and the scientific validity, analytical performance and clinical performance.

11. Dates and Signatures

Date and sign the plan. If your document management system supports it, you can digitally sign by typing e.g., your initials in the "Signature" field. Otherwise, you can still sign it the old-school way (print it and sign the sheet of paper, ugh).

Activity	Name	Signature
Creation		
Review		
Approval		

12. Qualification of the Responsible Evaluators

Attach CVs of the people who were involved in writing the Performance Evaluation. They must be "adequately skilled and trained".