INFORMATION FOR THE COMPLETION OF A SUBMISSION PACKAGE FOR THE WHO COORDINATED SCIENTIFIC ADVICE PROCEDURE FOR HEALTH PRODUCT R&D IN VITRO DIAGNOSTICS

The WHO Coordinated Scientific Advice (CSA) Submission Package should provide a ***comprehensive scientific overview of the product and its development programme***. The level of detail provided within each section will depend on the questions raised by the applicant and subject to CSA.

Applications should be uploaded in electronic format through a link provided by WHO.

1. STRUCTURE OF THE SUBMISSION PACKAGE

Applicants are requested to include a Table of Contents following the outline of this document and following instructions as provided in each section.

2. APPLICANT INFORMATION

Name of Organization		
Organization Address	Street Name and No.:	
	City:	
	Province/State:	
	Postcode:	Country:
Contact person	Name	
	Title	
	Email	
	Telephone number(s)	

3. SUMMARY OF PRODUCT CHARACTERISTICS

Product Name	
Other Product Names	
Assay format	*Please describe whether the assay is serological, nucleic acid based, for use with optical methods etc.*
Disease(s) or condition(s) addressed by the IVD	

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4. BACKGROUND INFORMATION

4.1. Disease or condition addressed by the product

Applicants are asked to describe the disease or condition being addressed by the product under development including its symptoms and outcomes if not d, the diagnosed and treated, the global disease burden and information on current standard of care. Please provide a list of references to support your statements.

4.2. Product information:

Applicants are requested to provide a detailed description of the product including:

- Principle of operation
- Intended purpose/use[1] including:
    - what is detected and/or measured;
    - the device's function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);
    - the specific information that is intended to be provided in the context of:
        - a physiological or pathological state;
        - congenital physical or mental impairments;
        - the predisposition to a medical condition or a disease;
        - the determination of the safety and compatibility with potential recipients;
        - the prediction of treatment response or reactions;
        - the definition or monitoring of therapeutic measures;
    - Whether it is automated or not;
    - Whether it is qualitative, semi-quantitative or quantitative;
    - The type of specimen(s) required;
    - The testing population;
    - For companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test;
- Likely product stability and storage requirements.

[1] The use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation. (REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

- The intended user of the IVD
- The intended use setting of the IVD (e.g., primary care clinic, district laboratory, regional or national reference laboratory).

5. SPECIFIC QUESTIONS FOR CSA

This section should include a rationale for seeking advice, with a clear, concise and unambiguous description of the question(s). Questions should be specific and clearly labelled according to the expertise required for the assessment and numbered sequentially. Applicants should also provide a position on each of the questions with an accompanying justification for the chosen methodology.

Questions should focus on data needs for **policy development and PQ processes**, e.g. review of proposed reference methods, specimen numbers, target population and intended use setting, stability.

4.3. Questions on PQ process

This section will include all questions pertaining to prequalification assessment requirements. For more information on requirements for IVDs please visit: https://extranet.who.int/pqweb/vitro-diagnostics/contents-dossier

4.4. Questions on policy development

This section will include all questions pertaining to requirements for WHO policy development and recommendations.

Note: Questions regarding issues that are relevant to both policy development and prequalification assessment will be clearly marked and labelled as such.

6. BACKGROUND

6.1. Quality background information

For all manufacturing site(s), describe the status/certification of the quality management system: if available, provide a certificate issued by a conformity assessment body or describe any plans for future certification.

6.2. Clinical evidence

Applicants are requested to include a list of completed, ongoing and planned studies. For each study, the following information should be provided:

- Study description
- Study identifier
- Study objectives and design features
- Specimens used
- Specimen characterization strategy and reference method(s)
- Type of user/operator
- Type of setting used (laboratory, hospital, primary care clinic, etc.)
- Date of initiation

- Date of completion/estimated completion
- Statistical methods planned/used
- A summary of study findings or expected outcomes.

For completed studies, information can be provided as a study report in the form of an annex.

6.2.1. Scientific validity[2]

In this section, applicants are requested to provide an overview of the scientific validity of the analyte measured by the IVD under development. Scientific validity may be derived from literature reviews where it is already well established and/or studies conducted by the product developer.

6.2.2. Analytical performance[3]

The application should include a detailed overview of the analytical studies completed and/or planned, e.g. validation of specimens, specimen stability, IVD stability, accuracy of measurement, analytical sensitivity and specificity, measuring range of the IVD etc. This section should describe the most important findings accumulated so far and identify any current challenges in the study plan.

6.2.3. Clinical performance[4]

The application should include a detailed overview of clinical performance studies completed and/or planned to support the intended use of the IVD under development including clinical sensitivity and specificity. This section should describe the most important findings accumulated so far and identify any current challenges in the study plan.

6.2.4. Additional evidence

This section should contain any additional evidence relevant to the questions raised and subject to CSA (e.g., safety considerations).

6.3. Additional elements of clinical utility[5]

Applicants are requested to describe any plans or guidance for evidence generation on clinical utility of the product.

6.4. Economic analysis

Applicants should describe any plans for economic analysis and describe the methodology selected to carry out the studies.

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[2] The association of an analyte to a clinical condition/physiological state.

[3] The ability of an IVD medical device to detect or measure a particular analyte

[4] The ability of an IVD medical device to yield results that are correlated with a particular clinical condition/physiological state in accordance with target population and intended user.

[5] The usefulness of the results obtained from testing with the IVD medical device and the value of the information to the individual being tested and/or the broader population.

All definitions according to: Clinical Evidence for IVD medical devices – Key Definitions and Concepts Study Group 5 Final Document GHTF/SG5/N6:2012

7. PREVIOUS SCIENTIFIC ADVICE RECEIVED

Applicants are requested to briefly describe any previous scientific advice received from other organizations (e.g. national regulatory authorities, notified bodies or health technology assessment organizations).

8. LIST OF REFERENCES

List of references: any relevant publications included in the list of references should be annexed (in searchable .pdf format).

9. LIST OF ANNEXES

Annexes should include any information potentially relevant to the questions subject to CSA, e.g.:

- Study protocols (final, draft or outline/synopsis)
- Study reports (final/draft/synopsis)
- Any published data

Note: press releases are not considered acceptable as a source of information.

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