WHO Coordinated Scientific Advice Procedure

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Emerging Technologies, Research Prioritization & Support

Research for Health Department

Science Division

World Health Organization

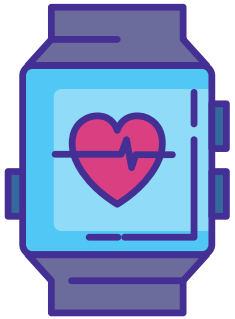
Where we fit in

THE SCIENCE DIVISION

Harnessing the power of science to achieve health for all.

Accelerating the impact of ethical research for people's health

RESEARCH FOR HEALTH DEPARTMENT



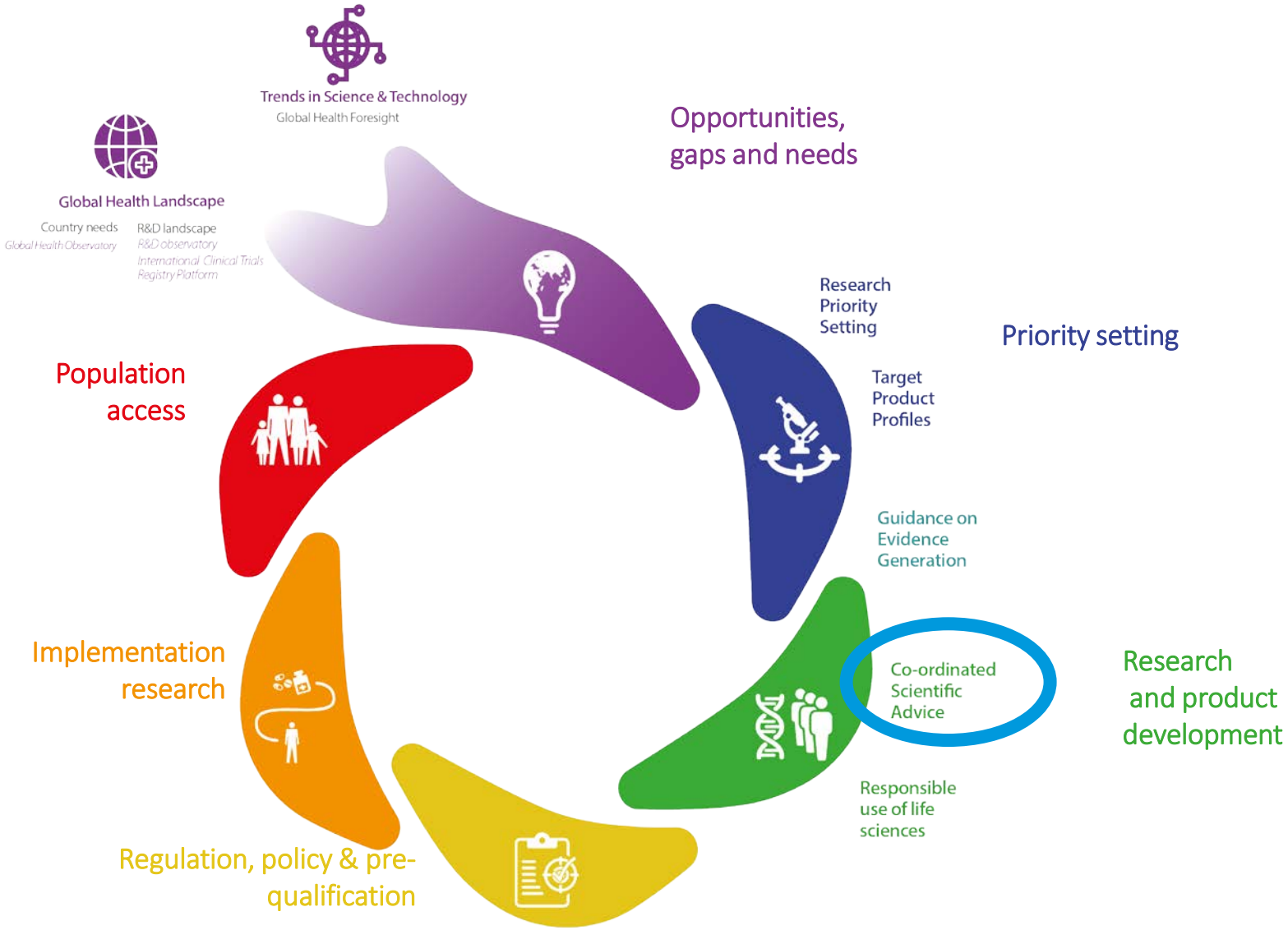
EMERGING TECHNOLOGIES, RESEARCH PRIORITIZATION AND SUPPORT

Optimizing and supporting Research and Development at WHO

Coordinated Scientific Advice

World Health Organization

R&D processes at WHO



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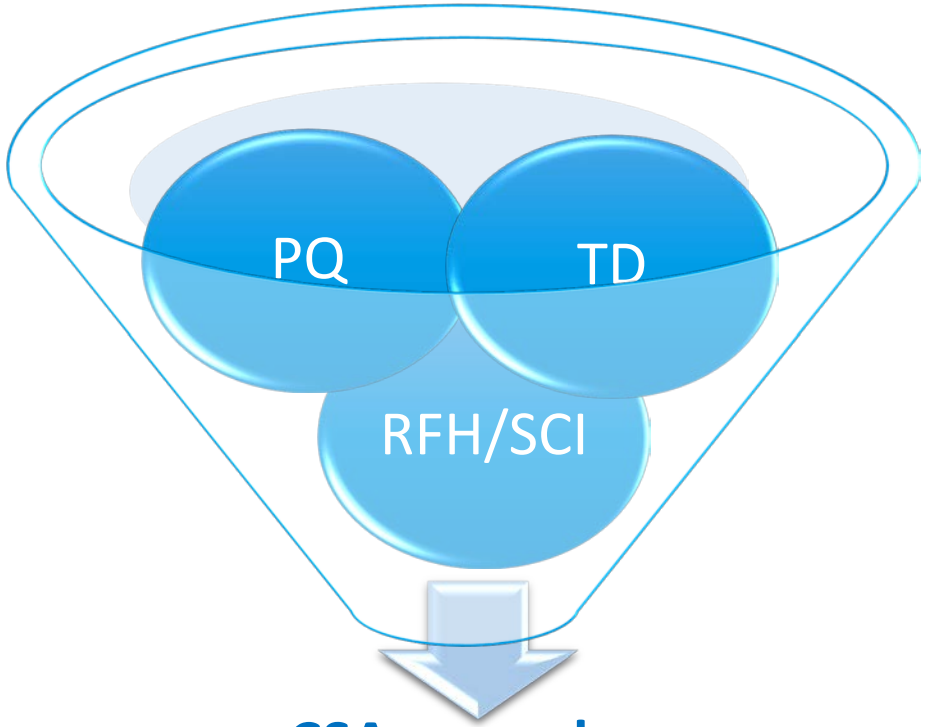
Outcomes: development of health products that address global health needs and accelerated implementation and uptake in countries

WHO Coordinated Scientific Advice (CSA)

WHO provides an **advice process** whereby **product developers** may approach WHO and obtain **joint advice** from **WHO Prequalification** and the **WHO Technical Department(s),** in areas of unmet public health needs.

Goal:

To expedite access to appropriate, quality, safe, efficacious health products



CSA procedure

PQ Prequalification
TD Technical Department
RFH Research for Health
SCI Science division

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Objectives of the CSA

Provide advice to developers seeking to develop a health product in line with WHO's expressed unmet public health needs

Ensure **good understanding of WHO Policy and Prequalification** data needs and processes and to provide **feedback on specific areas** of content for manufacturer's development plans

Accelerate timelines for provision of data in line with Policy development and Prequalification requirements and improve the quality of submissions received for these processes

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CSA - Key Principles

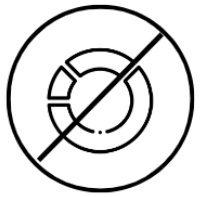
Voluntary

Confidential

Free of charge

Not binding

Impartial



Not a pre-evaluation of data,
Prequalification/Policy endorsement

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CSA – Eligibility

New products, new/additional data on existing products

Potential significant public health value

Within scope of WHO PQ – with exceptions

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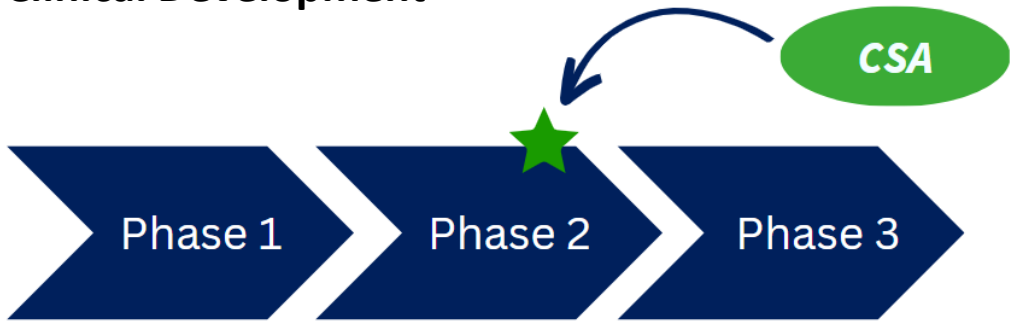
Questions for CSA and timing for submission

Product developers are expected to submit specific questions related to the following aspects:

- Quality
- Non-Clinical
- Clinical/epidemiological

Optimal timing will vary depending on product type.

Clinical Development



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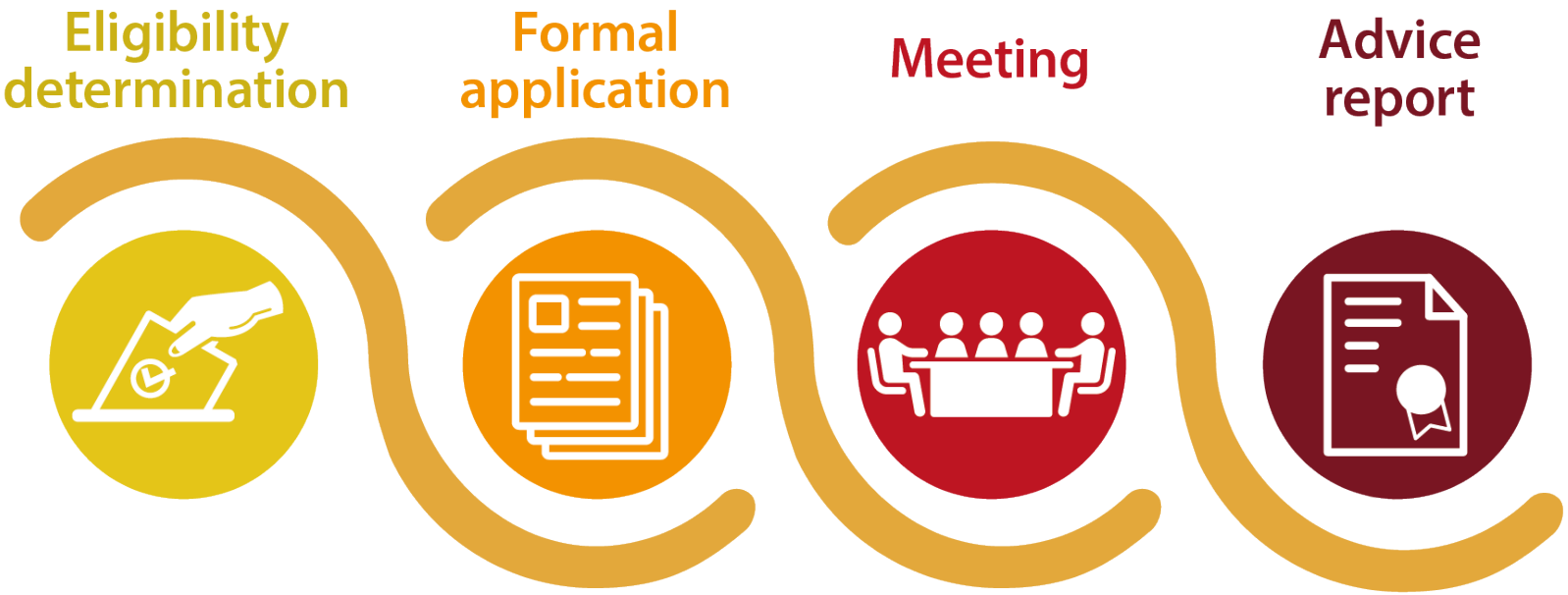
Pilot CSA - Key steps and Timelines



3 weeks for review, any requests for clarification and/or provisional responses to be sent ahead of the meeting to developer

Intended total: 10 weeks

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Benefits of the WHO CSA

- Standardized process: Submission
  Package template and explicit timelines
- Single entry point for developers
- Joint written advice from Technical Department(s)and Prequalification
- Expected impact for future Policy / Prequalification applications in terms of quality of submissions and possibly timelines to both outcomes.

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Pilot progress to date

14 CSA requests received

9 medicines

2 diagnostics

3 vaccines

12 requests accepted as eligible, 2 requests rejected

Average time during pilot: 85 days (~12 weeks > 10 weeks targeted time)

Evaluation through user survey feedback and targeted interviews identified a few areas for improvement.

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CSA and other Scientific Advice procedures

Other existing SA procedures:

- EMA Scientific Advice (SA, protocol assistance, SA on medicine repurposing, parallel SA pilot with FDA, parallel consultations with HTA bodies etc.)
- FDA
- In the context of a scientific opinion: EUM4All, Swiss MAGHP scientific advice with/without involvement from WHO and/or National Regualtory Authorities of targeted countries
- Other NRAs, local procedures

Processes in which WHO is involved are not exclusive. Developers are requested to mention previous interactions with national/regional regulatory authorities when approaching WHO for a CSA.

WHO CSA is specifically designed to advise on WHO requirements and not intended to provide advice to meet other NRA requirements.

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Thank you

For more information, please contact:
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Or visit our CSA website

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