As part of the methodology development process for the 2024 CSA, we kindly invite you to review a draft proposal for new and updated questions impacting your industry.

Please review this document and provide your feedback by completing the online survey.

The question texts and methodology presented may be subject to change at any time before the end of March 2024. In addition, questions may look different in the Online Assessment Tool in terms of question structure and layout.

| DEADLINE FOR FEEDBACK: | 19th February 2024 |
Introduction

Criterion Rationale

For executives, innovation is one of the key drivers of companies’ future success and therefore one of their top priorities. Innovation drives product, process and organizational change and is therefore the key differentiating factor for companies. Diverse types of innovation exist, including product and service innovation, focused on output, as well as R&D investments which aim to deliver value efficiently and effectively.

With this criterion, we capture and assess metrics related to product innovation launches, the condition of a company’s healthcare clinical pipeline, as well as innovating towards reduced-risk tobacco products.

Reason for update and summary of changes

This document contains the proposed changes to the existing questions “R&D Spending”, “Open Innovation”, “Product Innovations”, “Process Innovations”, “R&D breakout by Innovation Phase”, and “Product Innovations (Healthcare)”.

The questions “R&D Spending”, “Open Innovation”, “Product Innovations”, “Process Innovations” will no longer be part of the CSA. The theme of innovation continues to be an integral part of numerous other criteria outlined in the questionnaire where the topic of innovation incorporates the lens of the sustainable impact of innovations.

The criterion “Innovation Management” remains therefore only for the Tobacco industry as well as some of the Healthcare industries.

The question “Tobacco Alternatives & Reduced-Risk Products” will maintain its status as a critical component of the criterion for the Tobacco industry without any modifications.

The question “R&D breakout by Innovation Phase”, now referred to as “Healthcare Clinical Pipeline”, has received an updated breakout of the most distinct innovation phases, along with the new datapoints related to the number of projects pertaining to each of the phases, which aligns with the standards of reporting established by regulatory agencies and followed by healthcare companies. The revamped version allows companies to receive extra points for reporting publicly on their R&D spend breakdown or success rates associated with the listed phases. Given the distinct industry specifics, the question was removed for the Life Sciences
Tools & Services industry and will remain in the CSA for participants from the Biotechnology, Pharmaceuticals, and Health Care Equipment and Supplies industries.

Additionally, the question “Product Innovations (Healthcare)”, that is not updated, will only be allocated to the same industries for similar reasons.

**Updated Question**

*Healthcare Clinical Pipeline (ex-R&D Breakout by Innovation Phase)*

**INDUSTRIES IMPACTED:**

Kept for: BTC Biotechnology  
  DRG Pharmaceuticals  
  MTC Health Care Equipment and Supplies

Removed for: LIF Life Sciences Tools & Services

**QUESTION RATIONALE**

The innovation process within the healthcare industries is usually defined by several phases from pre-discovery to launch. With this question, we assess how healthcare companies establish, gauge, and monitor their innovation process across various phases.

**KEY DEFINITIONS**

Number of projects: The number of R&D projects associated with the listed development phases. Companies are requested to provide values for the number of projects along with the granular breakdown, which will allow for automatic calculation of the share of projects pertaining to each of the phases.

Success rate: The percentage of projects that move to the next phase.

Innovation: The process leading to the market launch of an invention. A differentiation is made between innovations that are new to the company and/or new to the market or industry and/or a worldwide novelty.

Discovery: In this phase, project leads identify that the market requirements and program assumptions merit advancement to full development. Depending on the industry, the scope of activities within the phase should include identifying lead chemical series while addressing unmet market needs or providing ‘proof of concept’.
Pre-clinical Development: This phase should result in determining design specification, completing lead optimization, and selecting preclinical candidates to enter enabling studies. For medical device producers, this stage includes activities related to laboratory and animal testing, as well as prototyping.

Clinical Trials: Phase I: This phase includes activities related to nonclinical pharmacological, efficacy, and safety studies resulting in a completion of initial drug characterization. It should result in meeting the set safety criteria, as well as assessing clinical readiness and the feasibility of full-scale manufacture of the future product. For medical device producers, the related set of activities should include assessing the initial safety performance on a limited number of participants.

Clinical Trials: Phase II: This phase should result in establishing optimal dose/parameters, as well as technology transfer to commercial facilities. For medical device producers, the studies conducted should include a larger and diverse group of patients compared to the previous phase. They should ideally provide preliminary evidence of effectiveness, guiding the design of subsequent phases.

Clinical Trials: Phase III: This phase should conclude by the preparation of comprehensive clinical trial reports with a full summary of the product’s clinical safety and efficiency in real-world conditions proven through the carried-out research.

Registration: This stage should result in achieving prequalification/local registration.

Launch: In this phase, the registered and approved product becomes commercially available. It undergoes post-market safety monitoring.

**DATA REQUIREMENTS**

Disclosure requirements for partially public question. Additional credit will be granted for relevant publicly available evidence covering the following aspect of this question in the most recent fiscal year:

- Percentage of R&D Spend on at least one of the listed phases.
- Success Rate associated with at least one of the listed phases.

Special note for MTC companies: should the suggested breakout of clinical trial phases not cover your company’s clinical development phases, please tick the relevant box under the table and provide information on the phases you use within your innovation process. Please note that the information will only be taken into account if the rows “Clinical Trials: Phase I”, “Clinical Trials: Phase II”, and “Clinical Trials: Phase III” are left blank.

**REFERENCES**


PMDA (Japan), Model informed drug development: https://www.pmda.go.jp/files/000209060.pdf

Previous layout

<table>
<thead>
<tr>
<th>Innovation phase</th>
<th>Share of R&amp;D budget invested (%)</th>
<th>Average duration</th>
<th>Average success rate ( % of products that move to next phase)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-clinical Research</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Research/Pathway to Approval</td>
<td></td>
<td></td>
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<tr>
<td>Launch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (must equal 100%)</td>
<td></td>
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</tr>
</tbody>
</table>

If the data cannot be aggregated at the company level, indicate which business unit you have chosen to represent in the table above, as well as the revenues generated by that unit (in % of total revenues):

- We do not track or measure R&D investments, durations, and/or success rates.
- Not applicable. Please provide explanations in the comment box below.
- Not known
Updated layout

**Notice:** Additional credit will be granted for relevant publicly available evidence covering the following aspect of this question in the most recent fiscal year:

- Percentage of R&D Spend on at least one of the listed phases.
- Success Rate associated with at least one of the listed phases.

### Healthcare Clinical Pipeline

**Please indicate the number of projects, breakout in R&D investments (% of total R&D spend), and success rates (%) for each of the phases of the healthcare innovation process below:**

<table>
<thead>
<tr>
<th>Innovation phase</th>
<th>Share of projects (%)</th>
<th>Number of projects</th>
<th>Share of R&amp;D budget invested (%)</th>
<th>Success rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>100.0%</td>
<td></td>
<td>100.0%</td>
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<tr>
<td>Discovery</td>
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<tr>
<td>Preclinical Development</td>
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<tr>
<td>Clinical Trials: Phase I</td>
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<tr>
<td>Clinical Trials: Phase II</td>
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<tr>
<td>Clinical Trials: Phase III</td>
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<tr>
<td>Registration</td>
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<tr>
<td>Launch</td>
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</tbody>
</table>

- Our company uses a different breakout for the clinical trial process. Please provide details:

- **PUBLIC REPORTING**
  - Our data is publicly available. Please provide supporting evidence or web link.
  - No references attached.

- We do not track the number of projects in our company’s innovation pipeline, the associated percentage of R&D, and success rates.
- Not applicable. Please provide comments in the explanation box below.
- Not known
Contact Us

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