PRIME Regulatory Roadmap and Product Development Tracker   
  
Notes for completion:

* This document is submitted via IRIS in Word format and is maintained **by the company**
* The document records both regulatory touchpoints (regulatory roadmap) and scientific product development aspects (product development tracker).
* Aspects **critical** to a specific development are the focus of the document. Not all areas will be applicable to all products, neither is the list exhaustive; specific areas can be added.
* It is advised that the company submits a new version whenever there are updates critical to development or evidence generation challenges (red areas). At this time, a cumulative update of other aspects (amber, green) can also be done.
* The impact on evidence generation is colour-coded by the company **based on their judgement**, and following regulatory touchpoints:
  + ***Low (Green)****: minimal challenges for future evidence generation, regulatory alignment on proposal for evidence generation*
  + ***Medium (Amber):*** *gaps that might impact evidence generation, possible divergence with advice or need follow-up dialogue*
  + ***High (Red)****: area of divergence/uncertainty expected to substantially impact upcoming evidence generation. This might also be used to highlight the need for rapid advice (see guidance for justification and applicability).*
* The first version of the document is submitted in preparation of the Kick-off Meeting, finalised following the discussion, updated across the lifecycle and reviewed at the submission readiness meeting.

**Regulatory Roadmap**

**A GANTT chart** (or equivalent) of planned global regulatory interactions should be attached, in a format chosen by the company but that should include regulatory interactions (including notified bodies and companion diagnostics, if relevant) and development milestones.

**Place GANNT CHART here**

**Product Development Tracker**

**Last UPDATED on DD/MM/YY**

**Product name/code/INN: <text>**

**RPI: <N>**

**Target condition and/or indication: <text>**

**Other product identification numbers (e.g. PIP, ODD): <text>**

**Planned date/type of next interaction: MM/YY, procedure**

**Target MAA date: QX YY**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| New in this update: | Area | Summary of the topic  (brief description) | Milestones | Impact on evidence generation  Low  Med  High | Company observations | SA planned/advised  (target date if known) | IRIS case number  of  previous SA/PIP/OD/ITF  on the topic |
|  | 1. **QUALITY** |  |  |  |  |  |  |
|  | Stability |  |  |  |  |  |  |
|  | Specifications |  |  |  |  |  |  |
|  | Manufacturing issues and process controls |  |  |  |  |  |  |
|  | Comparability  (changes to manufacturing process/site) |  |  |  |  |  |  |
|  | GMP Issues |  |  |  |  |  |  |
|  | Other (specify) |  |  |  |  |  |  |
|  | **II. NON-CLINICAL** |  |  |  |  |  |  |
|  | Carcinogenicity |  |  |  |  |  |  |
|  | Reprotox/Germ line integration |  |  |  |  |  |  |
|  | Animal model adequacy |  |  |  |  |  |  |
|  | Chronic toxicity |  |  |  |  |  |  |
|  | Immunotoxicity |  |  |  |  |  |  |
|  | Other (specify) |  |  |  |  |  |  |
|  | **III. CLINICAL**  **DEVELOPMENT** |  |  |  |  |  |  |
|  | Inclusion & Exclusion criteria |  |  |  |  |  |  |
|  | Adequacy of dose and/or regimen proposed |  |  |  |  |  |  |
|  | Choice of comparator |  |  |  |  |  |  |
|  | Trial duration |  |  |  |  |  |  |
|  | Endpoint choice |  |  |  |  |  |  |
|  | Choice of non-inferiority margin |  |  |  |  |  |  |
|  | PIP/paediatric data adequacy |  |  |  |  |  |  |
|  | Strength of evidence to address unmet need (note: include SB here if orphan) |  |  |  |  |  |  |
|  | Post-Authorisation Study Plan |  |  |  |  |  |  |
|  | GCP issues |  |  |  |  |  |  |
|  | Other (specify) |  |  |  |  |  |  |
|  | **Safety** |  |  |  |  |  |  |
|  | Safety dataset for MAA |  |  |  |  |  |  |
|  | Risk management |  |  |  |  |  |  |
|  | Other (specify) |  |  |  |  |  |  |
|  | **Statistical Methodology**  **Issues** |  |  |  |  |  |  |
|  | Other (specify) |  |  |  |  |  |  |
|  | **IV. OTHER DEVELOPMENT ASPECTS** |  |  |  |  |  |  |
|  | RCT approval challenges |  |  |  |  |  |  |
|  | HTA |  |  |  |  |  |  |
|  | Payer |  |  |  |  |  |  |
|  | Other regulatory agencies |  |  |  |  |  |  |
|  | Registries/RWE |  |  |  |  |  |  |
|  | Devices |  |  |  |  |  |  |
|  | Digital technologies/AI |  |  |  |  |  |  |
|  | Other (specify) |  |  |  |  |  |  |

**Interactions Roadmap and Development Milestones**

This section is optional. It can be used to record past and planned interactions by procedure type rather than content.

|  |  |  |  |
| --- | --- | --- | --- |
| Date | Interaction type | Main areas of discussion | Company observations |
| *DD/MM/YYYY* | *EMA Scientific Advice* |  |  |
| *DD/MM/YYYY* | *PRIME Kick-Off Meeting* |  |  |
| *DD/MM/YYYY* | *Scientific Advice from NCA* |  |  |