Template - Request for compliance check on an agreed paediatric investigation plan (PIP)

Procedure number:

Complete a table for each study, and copy & paste additional tables where required.

Ensure that agreed key elements are listed in the second column exactly as worded in the latest EMA decision.

Compliance check and evaluation

Quality-related studies

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of key element** | **Agreed key element (as per latest decision)**  | **Justification (Applicant’s position on fulfillment of the measures and timelines)** | **Location in the dossier** |
| ***Study identifier(s)*** | ***e.g. Study 1*** |  |  |
| e.g. Study description, objectives and outcome measure(s) | <Details here> |  |  |
|  |  |  |  |

Non-clinical studies

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of key element** | **Agreed key element (as per latest decision)**  | **Justification (Applicant’s position on fulfillment of the measures and timelines)** | **Location in the dossier** |
| ***Study identifier(s)*** | ***e.g. Study 2*** |  |  |
| e.g. Study description, objectives and outcome measure(s) | <Details here> |  |  |
|  |  |  |  |

Clinical studies

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of key element** | **Agreed key element (as per latest decision)**  | **Justification (Applicant’s position on fulfillment of the measures and timelines)** | **Location in the dossier** |
| ***Study identifier(s)*** | ***e.g. Study 3*** |  |  |
| e.g. Study description, objectives and outcome measure(s) | <Details here> |  |  |
|  |  |  |  |

Modelling and simulation analyses

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of key element** | **Agreed key element (as per latest decision)**  | **Justification (Applicant’s position on fulfillment of the measures and timelines)** | **Location in the dossier** |
| ***Study identifier(s)*** | ***e.g. Study 4*** |  |  |
| e.g. Study description, objectives and outcome measure(s) | <Details here> |  |  |
|  |  |  |  |

Other studies

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of key element** | **Agreed key element (as per latest decision)**  | **Justification (Applicant’s position on fulfillment of the measures and timelines)** | **Location in the dossier** |
| ***Study identifier(s)*** | ***e.g. Study 5*** |  |  |
| e.g. Study description, objectives and outcome measure(s) | <Details here> |  |  |
|  |  |  |  |