**Paediatric procedures: transition to IRIS**

Q. Which kind of changes will affect scientific documents in IRIS?

1. The scientific documents template has been simplified (e.g. comment boxes have disappeared) so, even if the concept will remain the same, the template will be slightly different and has been already published in the [specific page on the EMA website](https://www.ema.europa.eu/en/human-regulatory-overview/research-development/paediatric-medicines-research-development/paediatric-medicines-applications-procedures).

Q. When is it possible to input procedures on the IRIS platform?

1. Submissions for all paediatric procedures must be made in IRIS from 4 June 2024.

Q. Will the old procedures be migrated? When?​

1. Yes, migration of selected data from all previous paediatric procedures has been completed at the present time (October 2024). More importantly, all Paediatric Regulatory Entitlements (PIP or waiver granted) have been already migrated to IRIS, assigned to a LOC-ID of an organization, and are also visible in the public [Paediatric Register](https://iris.ema.europa.eu/pepublicregister/). For further details, please see also [Paediatric Regulatory entitlements in IRIS (Decisions on PIPs and product-specific waivers) · IRIS (europa.eu)](https://iris.ema.europa.eu/forums/whats-new/8255e1bf-c612-ef11-a81c-000d3a3890c1).

**PIP/waiver Regulatory Entitlements**

Q. After 4 June 2024, what is the process to notify the following changes:

a) change of PIP holder of an approved PIP or waiver?

b) change of applicant address?

c) change of authorized contact person?

d) change of contact for public enquiries?

1. a) and b): The IRIS platform allows industry users to transfer an existing PIP or Waiver granted to a different organization, or to a different location of the same organization. The process is automated and takes only a few minutes. For example, PIP holders may want to use the feature to assign all their PIP Regulatory Entitlements to the same location, which should normally be the legal seat of the organization.

c and d): The authorized contact person (who is not public) and the contact data for public enquiries (email and phone number) can be changed directly in the IRIS portal by any IRIS Industry user affiliated to the PIP/waiver holder. This is done by editing the regulatory entitlement record.

Q. Is there a requirement that a PIP related to an approved product is held by the same entity as the MAH? Or could it be a different entity of the same group?

1. A PIP or Waiver Regulatory Entitlement can be held by a different entity from that applying for or holding the marketing authorization. Please note that the same does not apply for orphan designations.

Q. When an initial PIP is modified, will the Regulatory Entitlement be modified as well?

A. Yes, in IRIS the (published) Regulatory Entitlements will retain the same number, but will be modified to include relevant changes, such as any new pharmaceutical forms and routes of administration, the type of entitlement (PIP or waiver), date of PIP completion, etc.

Q. Is it possible to search a submission by PIP number in the Industry Portal?

A. Industry users can list draft, ongoing and completed submissions in the Industry portal, for those submissions where they are listed as Industry Managers or Contributors. As before, Industry Global Coordinators can visualize all submissions. In addition, PIP/Waiver Regulatory Entitlements are public and can be searched and exported in the [Paediatric Register.](https://iris.ema.europa.eu/pepublicregister/) While direct searches in the Register can be done by name of active substance, condition, type of entitlement, Sponsor and date of decision, they cannot be done by PIP number. However, it is easy to export the entire list or a subset and perform a searches by PIP/waiver number in Excel.

Q. How will the ongoing PIP submitted before the go live (using previous processes) be handled after 4 June 2024?

1. Submissions sent before 4 June are being managed in the current (non-IRIS) process. However, at the end of the procedure immediately after the EMA Decision the Regulatory Entitlement will be migrated to IRIS, and will be visible in IRIS. Submissions will also be migrated to IRIS, at a later stage, including those withdrawn or not valid.

Q. How will the migration of procedures with clock stops to IRIS be handled, and when will the Regulatory Entitlements be created if the submission is before go-live?

1. Most PIP procedures in clock-stop have already been imported into IRIS, and therefore resubmission should be done in IRIS. A number of procedures which went into clock stop after the switch to IRIS have also been imported between June and October 2024. Please check the [What's New in IRIS](https://iris.ema.europa.eu/forums/whats-new) forum regularly, for any updates.

Q. At the time of PIP/Waiver Decision, will the information in IRIS be in line with the agreed PIP or not?

1. At present, the key elements of the agreed PIP are present only in the PIP Decision/Opinion document, they are not reimported as structured data into IRIS.

Q. How is a stepwise PIP meant to work in the system? ​

1. The stepwise PIP (sPIP) pilot will be managed as described in the available guidance. The submission of a sPIP application will work in IRIS in the same way as the regular PIP application.

Q. Would it be possible to copy an initial PIP procedure as starting point/baseline for modification procedures?​

1. Such functionality is not currently included in the system, because the outcome of the procedure will be a .docx document. However, it is certainly possible for applicants to extract the information from the Decision (which will be made available as .docx rather than PDF) and potentially re-use it in an in-house automation solution to provide data to the IRIS portal.

Q. What should I do when requesting a PIP if the pH value is not applicable?

1. A 0 can be entered if the pH value is not applicable. This is also explained in the error message generated if the field is left empty, and in the label of the field.

**Other questions**

Q. Can a user access the system if (s)he belongs to another organization?

1. Please see the [IRIS guide to Registration, Substances and RPIs](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration_en.pdf) in the [IRIS Guidance page](https://iris.ema.europa.eu/homenews/).

Q. Under “Quality”, if “Parenteral” under “General route of category” is selected, the following fields such as “Max dimension of solid”, “Max no. of capsules” are still mandatory even though these doesn’t apply to the Parenteral category, so 0.00 has to be typed to move to the next step. Is it possible to gray out these non-required boxes in situations where they do not apply?

1. Currently, this function is not available. If there is no information applicable for a specific field, then it is possible to type “0” or “N/A” to satisfy the validation rule.

Q. Isn’t there a higher workload to enter everything manually in the system (application form and key elements, all as drop down menus, etc.)?

1. The items in the web form are the same as those contained in the previous PDF forms (Part A plus key elements form). In fact, some simplification has been implemented for the details on the quality. As such, the portal web forms are expected to require the same time as the previous PDF forms or even less.

Q. Should the user be able to generate our data as documents for working/archiving, etc. together when we generate the “Application Form” Word document in IRIS?

1. The system offers the same feature already available for other process types, namely the generation of the application form with most of the structured data submitted in the portal. For the studies table of Initial PIP and Modification requests, not all the columns are included in the table of the .docx file generated, due to readability reasons. A user story has already been added to the IRIS backlog (see [Is it possible to extract the Key Binding Elements entered in IRIS for a paediatric submission?](https://iris.ema.europa.eu/forums/general-discussion/47936a29-e139-ef11-a81d-6045bd9be181)).

Q. Considering the number of internal stakeholders involved in generating key elements documents, Industry will most likely continue with a shared document for ease of coordination and IRIS access control, and compile data afterwards. It is not clear what the added value for EMA is, as the applicant can also give key elements in a document from the beginning as a .docx file. ​

1. Key elements proposed by Industry should be included in IRIS as structured data because of:​
   1. The key elements are different according to the type of study. This feature is automated in IRIS, while for .docx template it doesn’t apply.​
   2. The IRIS portal automatically specifies mandatory fields where appropriate (e.g., date of initiation and deferral for initiation are only mandated for clinical / non-clinical studies, but not for other study types).​
   3. Validation rules are implemented in the portal, to ensure that all required information is present. This reduces the risk of non-validation, or postponement/delay. ​
   4. The system is future-proofed for a possible further extension to complete management of the studies and key elements as structured data.

Q. Is there a timeframe provided for Industry to verify if the assigned Regulatory Entitlements are correct?

1. There is no specified timeline for this verification process. See [Paediatric Regulatory entitlements in IRIS (Decisions on PIPs and product-specific waivers)](https://iris.ema.europa.eu/forums/whats-new/8255e1bf-c612-ef11-a81c-000d3a3890c1) for more information.

Q. How are Art. 46 procedures managed when migrated to IRIS?

1. Art. 46 procedures are not specifically related to the paediatric procedures therefore they have not been migrated to IRIS yet. They will be moved to IRIS together with other centralised procedures.

Q. Are the Class Waiver decisions (subsequently implying a product waiver) meant to be reflected in the listing, either now or later, for completeness?

1. The Class Waiver decision, which is a single one, is included in the Regulatory entitlements list, as you can see in the [Excel file attached](https://iris.ema.europa.eu/forums/whats-new/8255e1bf-c612-ef11-a81c-000d3a3890c1) in the IRIS Forum.