



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Recent and upcoming developments of the IRIS platform for R&D processes

12th Industry stakeholder platform on research and development support

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An agency of the European Union





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Launch of the management of paediatric processes in IRIS





Q4 2023 – Q1 2024

Initial PIP, product-specific waiver, modification of agreed PIP, transfer of paediatric Regulatory Entitlement



Q2 2024

Discontinuation of paediatric development and confirmation of applicability of class waivers or of inclusion of an indication within a condition



Q1 - Q2 2024

Compliance check and annual reports



Go Live

4th June 2024





To improve our guidance, templates and IRIS experience, important to receive continuous feedback from Applicants. It will help us make the necessary adjustments and improvements.

Ongoing procedures, including procedures submitted by 3 June, will be finalised for Opinion/RfM with old system

Since 4th June, more than 80 paediatric procedures submitted in IRIS (all types).



Applicants start submitting applications via IRIS

From 4 June



First submission deadline window ends

8 July



Migration of cases in clock stop

(TBC) 8 July



First "Start of Procedure" in IRIS

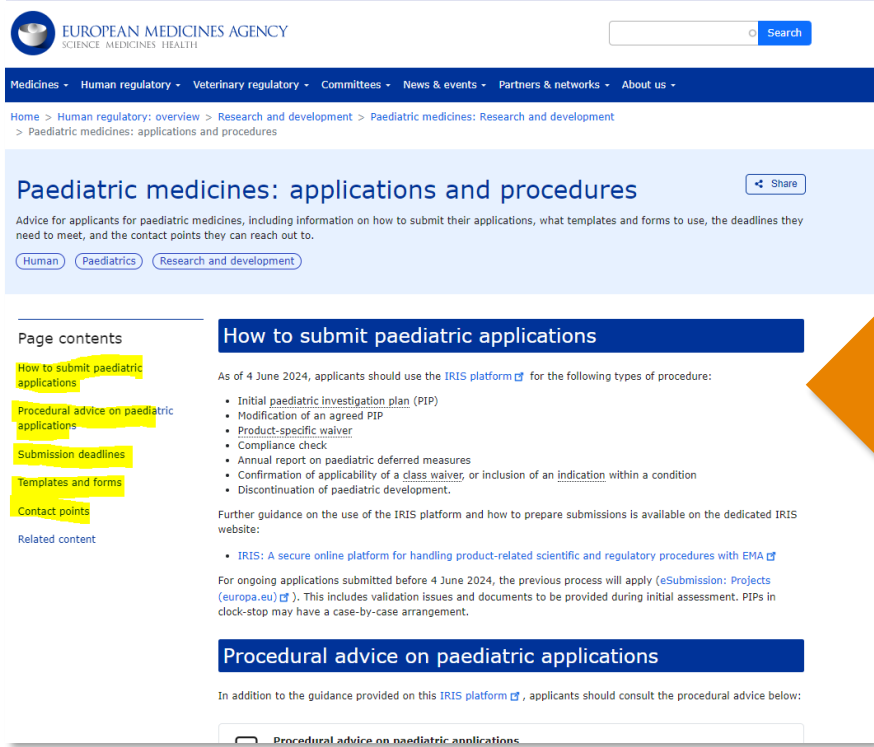
19 August



First discussion of procedures in IRIS

3 - 6 September

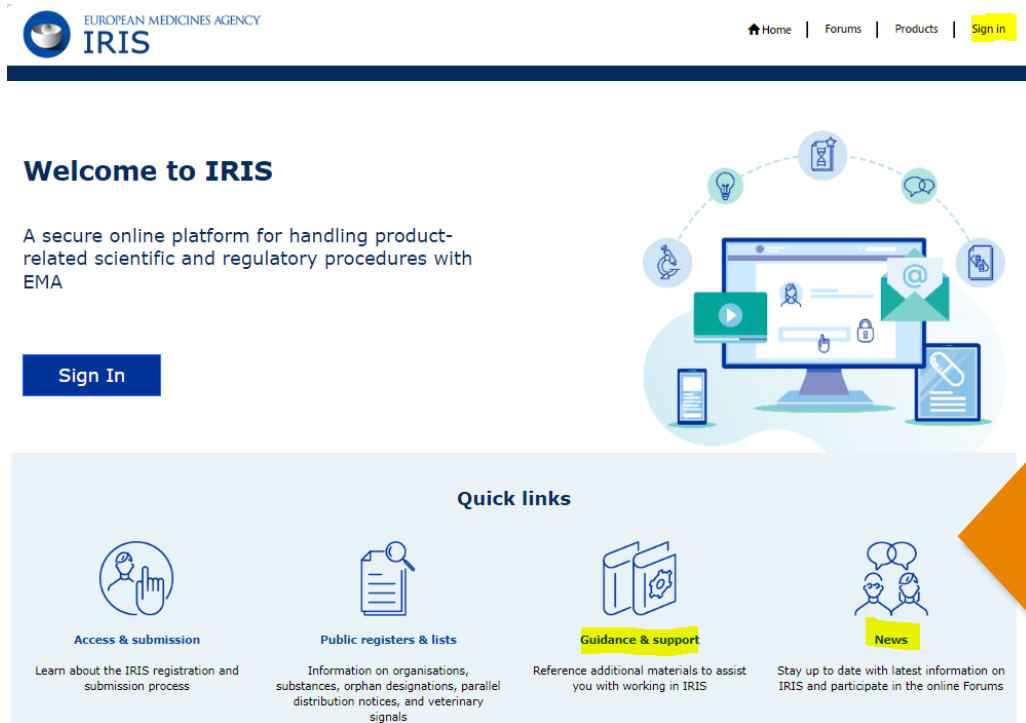
1st step: Visit the [Paediatric medicines: applications and procedures](#) page to access all the information necessary to prepare and submit a paediatric application:



The screenshot shows the EMA website page for 'Paediatric medicines: applications and procedures'. The page includes a search bar, navigation menu, breadcrumb trail, and a 'Page contents' section. The 'Page contents' section lists several topics, with 'How to submit paediatric applications' highlighted in blue. Below this, there is a section titled 'How to submit paediatric applications' which provides information about the IRIS platform and lists various types of procedures. Another section titled 'Procedural advice on paediatric applications' is also visible.

- Procedural advice
- Submission deadline
- Templates and forms (i.e. Scientific document, Key element guidance...)

2nd step: Visit the **IRIS** page to access technical guidance and IRIS-related forums, and to sign in to submit your paediatric application:



The screenshot shows the IRIS website interface. At the top left is the EMA logo and 'IRIS' text. A navigation bar includes 'Home', 'Forums', 'Products', and a highlighted 'Sign in' button. The main heading is 'Welcome to IRIS', followed by a sub-heading: 'A secure online platform for handling product-related scientific and regulatory procedures with EMA'. Below this is a 'Sign In' button. A central graphic depicts a computer monitor with various icons (lightbulb, microscope, mail, smartphone) around it. At the bottom, a 'Quick links' section features four icons with corresponding text: 'Access & submission' (hand pointing to a document), 'Public registers & lists' (document with magnifying glass), 'Guidance & support' (books), and 'News' (two people talking).

Guidance & support

Guidance

- IRIS guide to **Registration, Substances and RPIs**
- IRIS guide to applicants (**creation of submissions**)
- IRIS guide to parallel distribution applicants

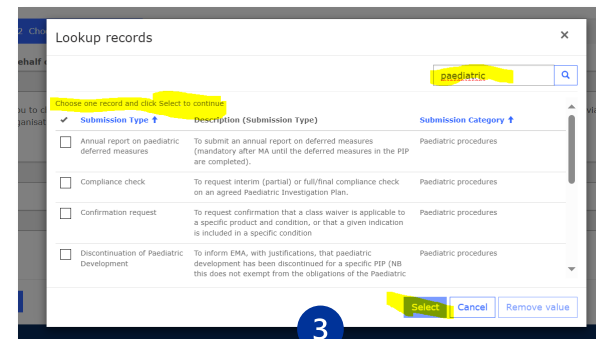
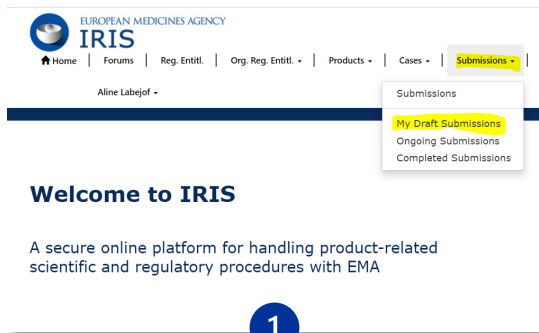
Additional guidance and training videos

• Guidance & support

- Registration, substances and RPIs
- Creation of submissions (see section 13 for paediatric applications)
- IRIS News/Forums (do not post confidential info!)



3rd step: Sign in to the IRIS portal and create a new submission following steps outlined in [iris-guide-applicants_en.pdf \(europa.eu\)](#) :



Relevant guidance sections:

- '2. Common operations for all submission types'
- '13. Paediatric medicines development'



Submission Form

Initial Paediatric Investigation Plan

Reference: EMA/PE/0000126075

Please make sure that the required sections have a green tick to the right (except "Documents from EMA") before submitting the application.

Customer Name : European Medicines Agency

Address : P. O. Box 71010 1008 BA Amsterdam Netherlands

Select OD/RPI

Updated information on RPI

Procedural Information

Scientific Information

Waivers

Quality aspects

Submission Notes

Documents from Applicant

Documents from EMA

Submit Application

Return

Generate Application Form

PIP condition.

Please specify only one **condition** to be covered by this PIP submission.
note: Create separate submissions for additional conditions.

Scope (diagnosis, prevention or treatment) *

Treatment of

Proposed medical condition to be covered by the PIP (Text) *

mature B cell neoplasms

Proposed medical condition to be covered by the PIP (MedDRA) *

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Proposed adult indication(s) within the condition above (text) *

Treatment of adult patients with relapsed or refractory non-Hodgkin lym

Proposed PIP paediatric indication(s) within the condition above (text) *

Treatment of relapsed or refractory Burkitt lymphoma

'Submit Application' becomes clickable when all sections and mandatory fields are filled in.

IRIS Demo:

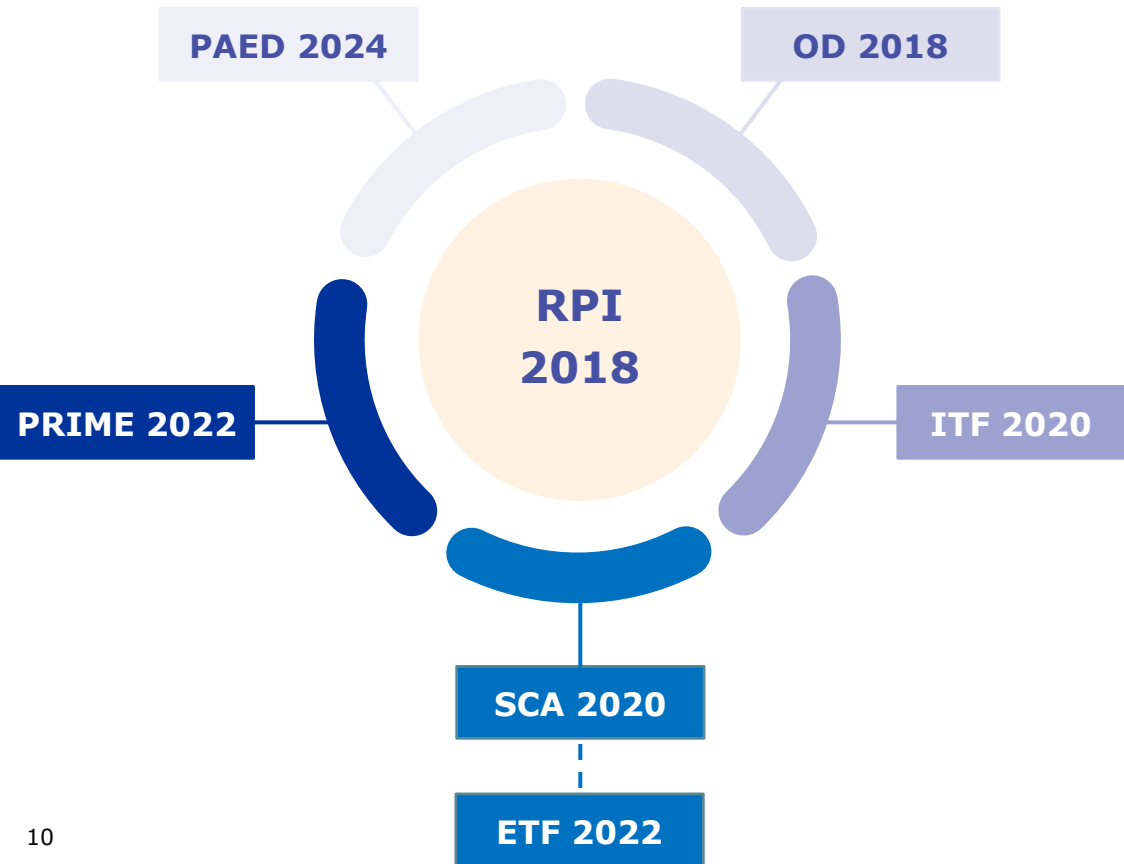
- [EMA Quarterly System Demo Q42023](#) - 19 December 2023 available on EMA website (video with example of PIP application, from 58:00 to 1:10:45)
- [EMA Quarterly System Demo Q12024](#) - 26 March 2024 available on EMA website (video with examples for 3 procedures, from 4:04:00 to 4:25:47)

IRIS Guidance:

- [Guidance and support](#)
- [IRIS Stakeholder Forums](#)

Need help?:

- For access and registration requests and for reporting technical faults: [EMA ServiceNow](#)
- For general question related to paediatric application (i.e. question on content of paediatric submission, paediatric regulatory questions) [Ask EMA](#)



- ### Benefits for applicants
- One single interface for submissions and related communication (OMS and IAM integration) simplifying interaction with EMA
 - Online monitoring of application process
 - Online monitoring of RPIs, REs, cases
 - Data entry automations
 - Increased security (access and document exchange)



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Value of the RPI concept



NAME OF PRODUCT CHANGES:

- **Company code(s):**
- **Descriptive name**
- **Scientific Name**
- **Chemical name** (which classification?)
- **ATC** (only available late – multiple codes for FDCs)
- **INN** (only available late)

APPLICANT CHANGES:

- Sold / transferred to another developer
- Mergers
- Co-developed
- Regulatory consultant hired for EMA submission

Name in orphan designation	Current name of product in RPI
Human IgG1 monoclonal antibody against Sortilin	Latozinemab
humanised IgG2k Fc-modified bispecific monoclonal antibody against CD3 and BCMA	Elranatamab
(S)-5-amino-3-(4-((5-fluoro-2-methoxybenzamido)methyl)phenyl)-1-(1,1,1-trifluoropropane-2-yl)-1H-pyrazole-4-carboxamide	Pirtobrutinib

EMA receives submissions for the **same development product** with:

- Different name of applicant
- Different name of product

Difficulties in proactively following development across lifecycle



- Check your RPIs in IRIS, with ADIS link and location ID: [Portal – RPIs](#)

- RPI required for most development submissions (ITF, PRIME, Orphan, Scientific Advice, Paediatric)

- RPI not required for submissions based on existing Regulatory entitlement (Annual reports, follow-up SA/PA, PIP modification, compliance check, etc.)

- RPIs can be transferred by Industry (self-service)

Present

- Integrated information on global product(s) development, from internal and external sources, readily available to EMA staff, Committees and Working Parties

- Data provided to internal AI tools

- Improved consistency, relevance and overall quality of EMA output

Benefits

- Sponsors will be able to directly update selected RPI data via IRIS portal anytime

- Integration of RPI with other identifiers

Future



Any questions?

Further information

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Send us a question Go to www.ema.europa.eu/contact

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