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SCIENCE MEDICINES HEALTH

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

11th Industry stakeholder platform on research and development support

Tarita Toufexi and Anna Gross 4 December 2023
Scientific Evidence Generation Department, EMA

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Additions to the management of PRIME

Planned onboarding of paediatric processes

PRIME onboarding to IRIS - completed

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Go-live July, 10 2023

✓ Application for PRIME eligibility

✓ Transfer PRIME regulatory entitlement

✓ Withdrawal of PRIME regulatory entitlement

Go-live October, 3 2023

✓ PRIME meeting request
incl. Kick-off meeting, introductory meeting, ad-hoc meeting, submission readiness meeting, pre-submission meeting

✓ PRIME Periodic update submission

PRIME onboarding to IRIS – PRIME meeting request

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Home > Ongoing Submissions > **Submission Form**

Submission Form

Customer Name : European Medicines Agency
Address : Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands

Meeting Information
Documents from Applicant
Documents from EMA
Submit Application

Return

Withdraw Submission | Generate Application Form

PRIME onboarding to IRIS – PRIME meeting request

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Home > Draft Submissions > Submission Form > **Meeting Information**

Meeting Information

Please select the meeting type *

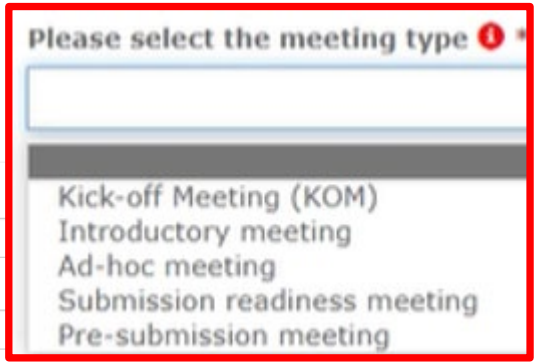
Please select the Regulatory Entitlement (If Applicable)

Proposed Meeting Date (e.g. - 02/Jul/2023; 15/Aug/2023) *

For kick-off meeting, please put 2 hours slot / CET time zone. For Introductory, pre-submission and ad-hoc meetings, please put 1 hour slot / CET time zone.

Additional Comments

Save and Return | Return



PRIME onboarding to IRIS – PRIME periodic update

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Home > Draft Submissions > **Submission Form**

Submission Form

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 : Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands

Regulatory Entitlement
Procedural Information
Submission Pipeline
Submission Notes
Documents from Applicant
Documents from EMA
Submit Application

Return

Generate Application Form

Procedural Information

Development ongoing: *
(•) No ( ) Yes

Reason for discontinuation of development *

PIP Agreed *
( ) Yes ( ) No

Have you received Scientific Advice/Protocol Assistance since the last periodic update? *
( ) Yes ( ) No

Are you requesting an expedited advice with this submission? *
(•) No ( ) Yes

Save and Return | Return

PRIME onboarding to IRIS – PRIME periodic update

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Submission Pipeline

Please select the RPI for this submission: *

PRD/0001201163

Information on Submission Pipeline (Please note this is read only information from RPI)

Foreseen date of the next Marketing Authorization application submission for this RPI

13/08/2024

Foreseen legal basis of next Marketing Authorisation application submission for this RPI

Full application (Article 8(3) of Directive No 2001/83/EC)

Foreseen date of MAA submission was last updated on

14/11/2023

Applicant's reason for changing MAA forecast

test 12345

Update Information on Submission Pipeline

Note: Please note that the information on the submissions pipeline is recorded on the RPI, any changes made here will be synchronized with the RPI record.

Please confirm these information are up to date *

○ Yes ◉ No

Foreseen date of the next Marketing Authorization application submission for this RPI: *

DD/MM/YYYY

Foreseen legal basis of next Marketing Authorisation application submission for this RPI *

Applicant's reason for changing MAA forecast *

PRIME onboarding to IRIS – useful links and next steps

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- Industry public DEMO available on EMA website from September, 21

  (Demo on PRIME meeting request and periodic update submission)

- Update of PRIME landing page on EMA website on how to apply via IRIS

- Update of PRIME Guidance for applicants

User experience - short survey to follow up

Paediatrics – IRIS Roadmap

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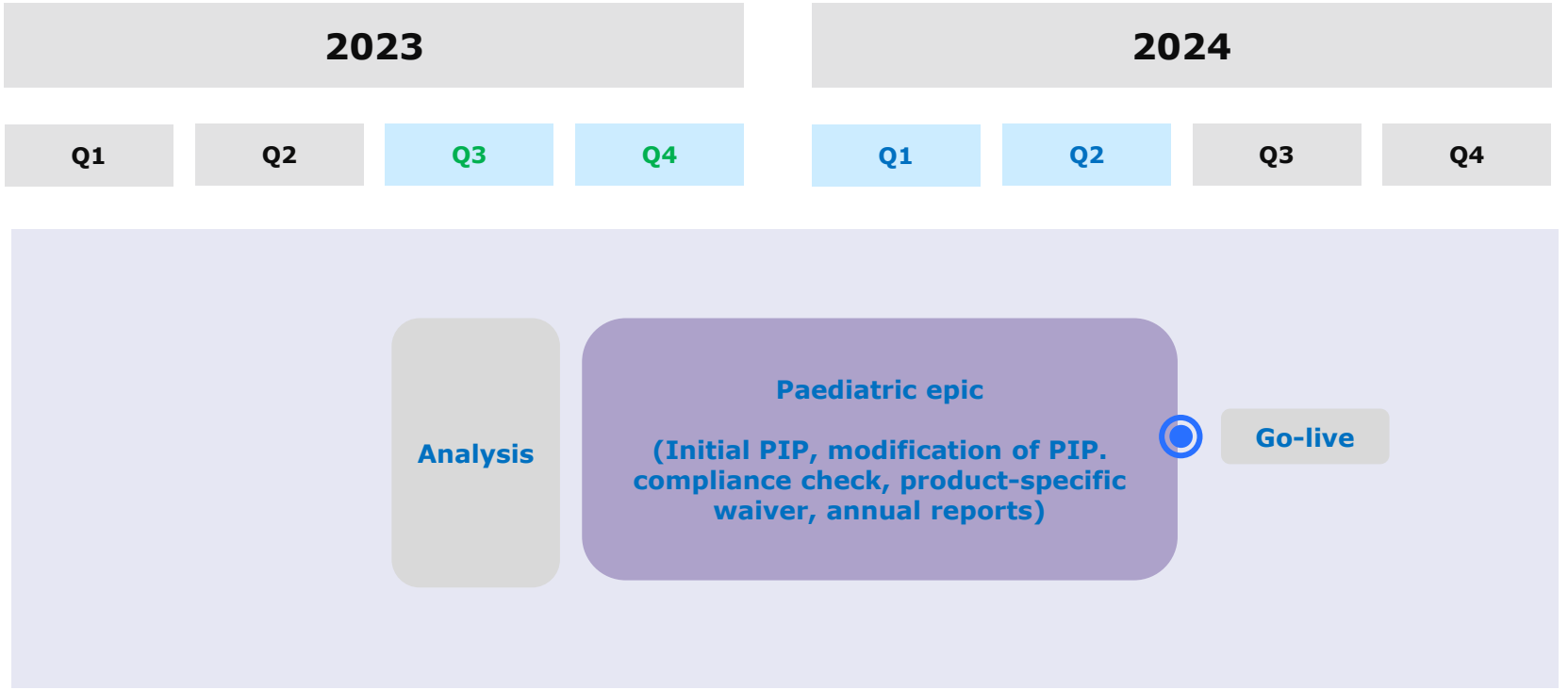

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Quarterly system demo - Q4 2023

Date: 19/12/2023

Location: Online. 9:00 - 14:00 Amsterdam time (CET)

The system demo will provide an integrated view on what has been built in the past 3 months (Programme Increment). Each demo has a dedicated timeslot on the agenda. The event is broadcast live. A video recording will be made available after the event.

Initial Paediatric Investigation Plan

Live broadcast

Agenda - System Demo Q4 2023 - 19 December 2023 Public - DRAFT (europa.eu)

Quarterly system demo - Q4 2023 | European Medicines Agency (europa.eu)

Paediatrics – Looking for volunteers!

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What does this entail?

- Participation in a few webinars (demonstrations and feedback);
- Feedback on user guidance and promote its sharing and training at industry level;
- Stay up to date on implementation of IRIS for Paediatrics processes and cascade information within the respective organisations;

Who can participate?

- People who have had experience with IRIS before
- People with no previous IRIS exposure but have submitted regulatory applications via other systems

What to expect?

Feedback sessions will take place in Q1 and Q2 2024 and would require about 2 hours per month. The request for nomination will be sent via trade associations with a deadline for nominations on 18 December 2024.

We look forward to working together on Paediatrics,
for the benefit of public health and regulatory systems!

Any questions?

Further information

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

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