

# IRIS Roadmap updates & Updates to Industry Contact Management for Authorisation Products

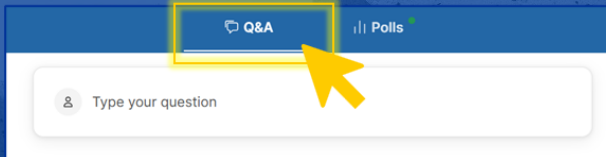
11 June 2026, 11:00 – 12:15 (CEST)

Post-webinar edit: the Survey will stay open until 20 June

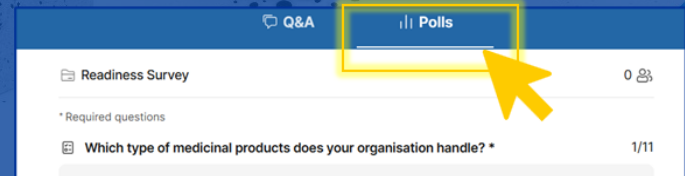


Please note that **this session is being recorded.**

During the session, participants will be able to **ask questions** via the audience interaction tool **Slido**  
(Slido code: #IRISSURVEY or scan the QR code)



We will also invite you to **provide feedback** on IRIS and the **go-live of pre-submission and iMAAs** through a **survey** that will be launched at the end of the session (Slido code: #IRISSURVEY or scan the QR code).



Interaction via Slido is voluntary, and you may opt to remain anonymous.  
If you chose to use Slido, **you consent to the processing of your personal data** as explained in the [EMA Data Privacy Statement for Slido](#).

# Agenda

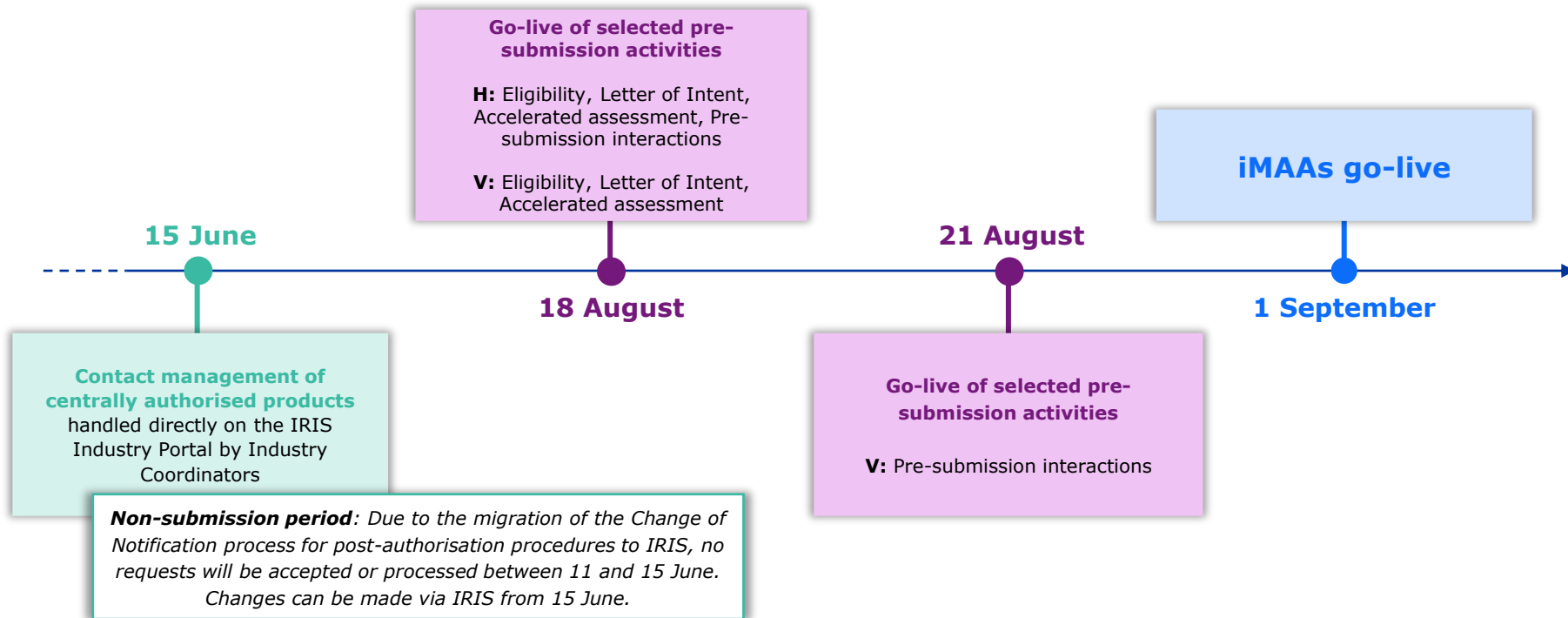
<b>1</b>	<b>Welcome &amp; Opening</b>	<b>5 MIN</b>	<b>Irene Mumeni Urbani,</b> <i>RPM for PLM Change Management Team</i>
<b>2</b>	<b>IRIS Roadmap updates</b>	<b>5 MIN</b>	
<b>3</b>	<b>Management of authorisation product contacts – key changes</b>	<b>15 MIN</b>	<b>Simona Griniene,</b> <i>Subject Matter Expert for Regulatory Procedure Management, EMA</i>
<b>4</b>	<b>Management of authorisation product contacts – live demo</b>	<b>15 MIN</b>	
<b>5</b>	<b>Q&amp;A session</b>	<b>20 MIN</b>	
<b>6</b>	<b>Survey &amp; Closing</b>	<b>15 MIN</b>	<b>Irene Mumeni Urbani,</b> <i>RPM for PLM Change Management Team</i>

2 Join SLIDO to ask Questions: #IRISSURVEY

# 2

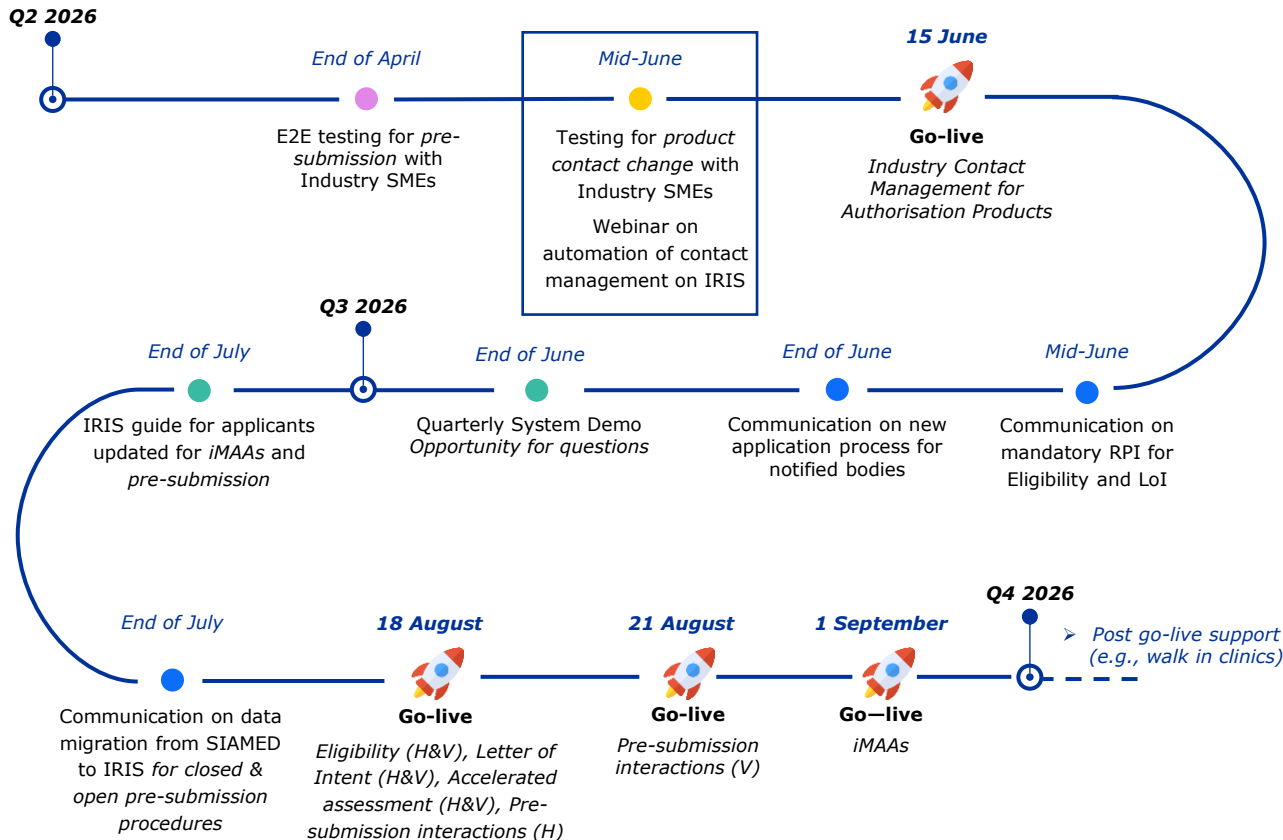
## IRIS Roadmap updates

# Upcoming milestones for Industry users



As these milestones approach, a range of **support activities** will be provided to Industry users to facilitate the transition to IRIS.

# Change Management Activities



## Support ecosystem

- Biweekly engagement with Industry SMEs for Epic 3 procedures (Engagement)
- Ad hoc updates to the Industry FAQ (Engagement)
- Walk-in clinics (from September, 2 times per week) (Communication)
- Additional support as needed (Engagement)

## Legend

- Engagement
- Testing activities
- Training/ Guidance materials
- Communication

# 3

## Management of authorisation product contacts

*Key Changes*

# Contact Management: Current Process and Transition to IRIS

## Today

(until 10 June)

MAH product contact changes (The Change of Notification process) are currently to be submitted to EMA **by MAH via Service Now**

## During the transition

(11 June – 14 June)

**Service Now will be no longer available** for Change of Notification submissions for post-authorisation procedures.  
***The tickets with pending MAH clarifications will be closed as unresolved.***

## After go-live

(From 15 June)

- Contact management starts via **IRIS Industry Portal**
- It will be managed directly **by IRIS Industry Coordinators**
- **All products and contacts** will be **visible** via IRIS Industry Portal

# MAH contacts creation in IRIS (1<sup>st</sup> time)

Name of the role			
<b>Pre-submission product contact</b>	Created at the time of Eligibility (H) and Eligibility and LoI (V) submission. Submission contact = Pre-submission product contact in IRIS	Main MAH product contact until submission of iMAA	Pre-submission
<b>Person authorised for Communication on behalf of the Applicant during the Procedure</b>		Main MAH product contact until the Marketing authorisation is granted (i.e. up to when the Commission decision is received).	Pending
<b>Proposed Marketing Authorisation Holder/Person</b>			
<b>Person authorised for communication between MAH and Authorities after Authorisation</b>	Created at the time of submission of iMAA (eAF)	Main MAH product contact for all post authorisation procedures	Valid
<b>Person responsible for Product Defects/Recalls</b>			
<b>Person of the MAH in the EEA (acc. Article 98 of Directive 2001/83/EC) (<i>H product only</i>)</b>			

# Centralised product MAH contact roles

Name of the role	Description	IRIS Manager role is mandatory
<b>Pre-submission product contact</b>	This contact is only used <b>until the initial marketing authorisation application</b> is submitted ( <i>When pre-submission procedures go live in IRIS</i> ).	Yes
<b>Person authorised for Communication on behalf of the Applicant during the Procedure</b>	Referred to in section 2.4.2 of the application form <b>for initial marketing authorisation application</b> . This contact is only used until the Marketing authorisation is granted (i.e. up to when the Commission decision is received).	Yes
<b>Proposed Marketing Authorisation Holder/Person</b>	Referred to in section 2.4.1 of the application form for initial marketing authorisation application. The telephone number must correspond the country of the official Marketing Authorisation Holder address (SmPC section 7 for human products). It will be used <b>for delivery of all Commission decisions</b> .	Yes
<b>Person authorised for communication between MAH and Authorities after Authorisation</b>	Referred to in section 2.4.3 of the application form for initial marketing authorisation application. This contact will be used <b>after the Marketing authorisation is granted</b> (i.e. from when the Commission decision is received).	Yes
<b>Person responsible for Product Defects/Recalls</b>	Referred to in section 2.5.1.1 of the application form for initial marketing authorisation application.	No
<b>Person of the MAH in the EEA (acc. Article 98 of Directive 2001/83/EC)</b>	Referred to in section 2.4.5 of the application form for initial marketing authorisation application ( <i>for Human products only</i> ).	No

# Actions for Marketing Authorisation Holders (MAHs)



Ensure that your MAH **has IRIS Industry Coordinator appointed**.



**Check** all the **current contacts** available in IRIS for your centralised products **and amend** them accordingly via IRIS portal.



Ask new contacts for the roles with mandatory IRIS access to request **IRIS manager role from the MAH of the product** with individual email address



Ensure that *Proposed Marketing Authorisation Holder/Person* (for delivery of all Commission decisions) **has telephone number** corresponding the country of the official Marketing Authorisation Holder address (SmPC section 7 for human products).

*The amendment to the phone number must be done **by contact person** itself **via IRIS profile page** (see IRIS guide for Applicants).*

# Key things to remember

## UPDATING CONTACTS ON ONGOING CASES IN IRIS

The change of MAH product contact **does not automatically update contacts for ongoing cases** in IRIS. The MAH needs to change them separately. All information on how to change MAH product contacts and MAH contacts for cases will be available on [IRIS guide for Applicants](#).

## UPDATING CONTACT FOR ONGOING CASES NOT IN IRIS

For ongoing MAAs or other procedures not in IRIS, the request to change MAH contact **needs to be sent to procedure lead (H) or procedure coordinator (V) via email**. In addition, the MAH need to update MAH contacts for its pending products via IRIS portal.

## ASMF CONTACT MANAGEMENT

Until further notice, **ASMF contacts will not be managed in IRIS**. The ASMF contact will be retrieved from the EctD Sequence (H) or Vnees dossier (V) of the relevant submissions by EMA procedure team.

## VISIBILITY OF EMA RESOURCES

**Rapporteurs of the products and EMA resources** will be made available for IRIS Industry Coordinator and for product contact via IRIS portal under Centrally authorised products for my Organisation tab (*to be implemented in due course*).

## NO USE OF FUNCTIONAL EMAIL ADDRESSES

**No functional emails** are supported in IRIS and will cause issues with the communication.

# IRIS User access roles - Recap

Figure 9 in the [IRIS guide to Registration and RPIs](#). For more details, please check the guide.

IRIS user access roles					
Activity	User Admin	Manager (who is also a Submission/ Portal contact)	Contributor	Coordinator	IRIS Individual user
Approve IRIS Industry/Parallel Distribution Users in EMA Account Portal	√				
Create/delete/submit their own draft submissions in IRIS Portal			√		√
Edit/view/withdraw their own submissions in IRIS Portal			√		√
Edit/view specific submission in IRIS Portal			√		
Allocate managers/contributors to their own and specific submissions in IRIS Portal			√		
Reassign submission/portal contact to their own and specific submissions in IRIS Portal.			√		
Edit/view all submissions in IRIS Portal made on behalf of an organisation				√	
Allocate managers to all submissions made on behalf of an organisation				√	
Reassign submission/portal contact to all submissions made on behalf of an organisation				√	
<b>New</b> View and manage MAH contacts for centrally authorised products				√	

# 4

## Management of authorisation product contacts

*Live demo*

# Demo time



**Management of  
authorisation product  
contacts**



# Where to find IRIS Guidance and Support



## [IRIS Guide for Applicants](#)

Comprehensive **step-by-step guidance** to create, submit and manage IRIS applications

Portal to **raise a ticket for technical assistance**, including issues related to access, accounts, submissions or system functionality



## [EMA Service Desk \(ServiceNow\)](#)

*Do you need support?*



**IRIS**

## [IRIS guide to Registration and RPIs](#)



**Detailed preliminary requirements** for all IRIS submissions, including substance and Research Product Identifier registration

Brief document that lists and describes the **new features and fixed issues** included in the release of the IRIS Portal

## [Public Release Notes](#)



# 5

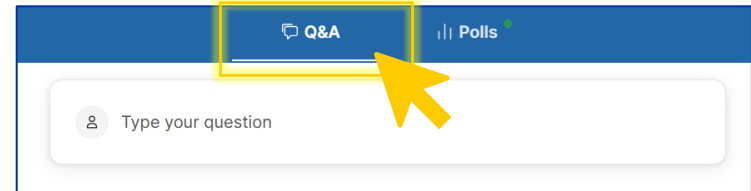
## Q&A



# Q&A

You can ask questions or give your input via the audience interaction tool **Slido**.

1. **Join at [slido.com](https://www.slido.com)** with the code #IRISSURVEY or by scanning the QR code below.



2. **Select the section “Q&A”** and **send or upvote the questions** you want to hear answered
3. **Questions will be shown on the screen** and **answered live** in the Q&A session

# 6

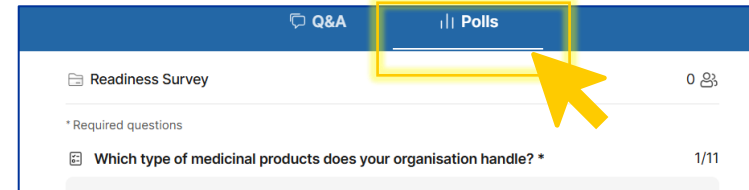
## Survey

Post-webinar edit: the  
Survey will stay open  
until 20 June

# IRIS Readiness survey

We would like to **hear from you** about **IRIS!**

1. **Join at [slido.com](https://www.slido.com)** with the code #IRISSURVEY or by scanning the QR code below.



2. **Select the section "Polls"** and complete the short readiness survey.

Your feedback will provide **valuable insights** into stakeholder **awareness**, **preparedness** and **expectations** ahead of the transition.



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# Thank you

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