EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Updates on IRIS Platform

Future approach in the context of Agile and update on Marketing Status and Inspections

Presented by: **Karl Hamilton**, Product Lifecycle Management Value Stream Owner
and **Pedro Pina Ferreira**, Monitoring Value Stream Owner

Digital Business Transformation Task Force

Agenda

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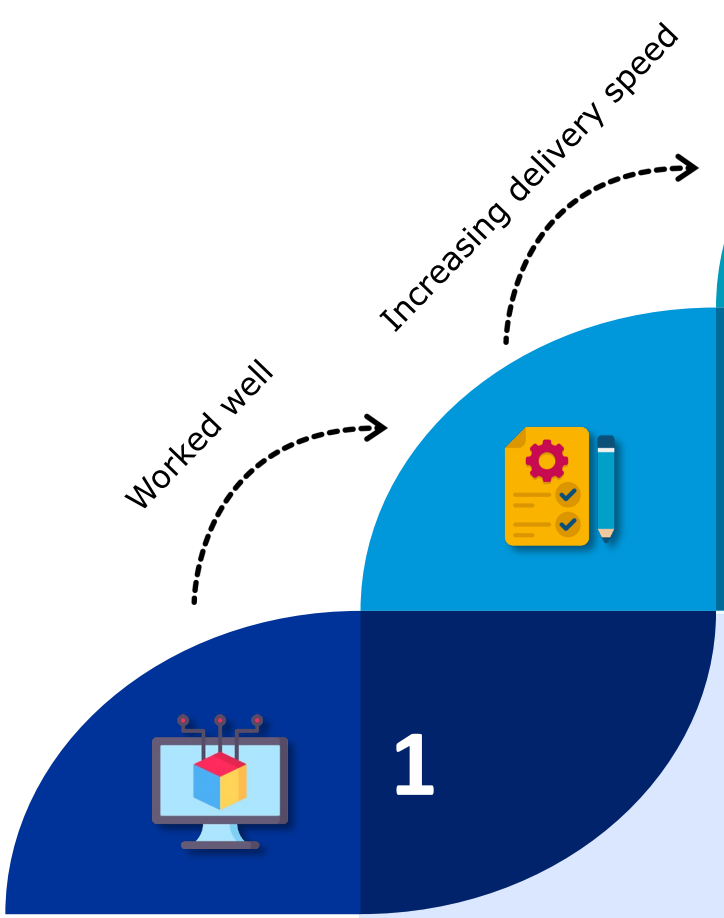
1	**Welcome**	***Karl Hamilton*** *Product Lifecycle Management Value Stream Owner*
2	**Update on Agile Transformation and impact on former IRIS governance**	***Karl Hamilton*** *Product Lifecycle Management Value Stream Owner*
3	**Update on GxP Inspections and Marketing Status**	***Pedro Pina Ferreira*** *Monitoring Value Stream Owner*
4	**Brief update on DADI UAT**	***Karl Hamilton*** *Product Lifecycle Management Value Stream Owner*
5	**Questions / discussion**	

Update on Agile Transformation and impact on former IRIS governance

Presented by: **Karl Hamilton**, Product Lifecycle Management Value Stream Owner

IRIS at scale



- Multiple development teams working on IRIS in parallel
- Adopting governance that allows clearer prioritisation of work and enablers (SPOR)
- Critical choices on MVPs that minimise the risk of issues
- Iterative improvement

Inspections procedure implementation showed what would need to change to:

1. Optimise/improve integration with SPOR
2. Reduce risks posed by legacy data and system architecture

A single development team working in IRIS, implementing 1-2 relatively standalone procedures at a time with clear industry involvement

Agile & IRIS

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IRIS is not a product – it was and is a **platform** that facilitates multiple procedures.

Procedures for related products are clustered in **value streams** – value streams ensure there is learning within and among value streams, supported by the IRIS platform team and cross-value stream roles.

IRIS will continue to be supported by a **platform team responsible** for technical consistency as multiple development teams work to deliver release on IRIS.

Approaching **development in an Agile way** helps prevent siloes while we scale up work done on the IRIS platform (architects, cross-team roles, shared planning events).

EMA is pursuing Agile to **eliminate silo working** by linking work, setting clear priorities and having shared planning events with delegated decision making.

Research and Development

Regulatory Procedure Management for Research and Development

- Orphan Designation
- Scientific Advice
- Innovation Task Force

Emergency Task Force (ETF)

To be onboarded:
T.R.I.P., Clinical Trials Information System (CTIS), DARWIN EU, LRSR, LRSM

Product Lifecycle Management

Regulatory Procedure Management for Product Lifecycle Management

- Initial Marketing Authorisation
- Variations
- Transfers, Renewals, PAMs, etc.

Digital Application Dataset Integration (DADI)

Medicinal Product Data (PMS)

Electronic Product Information (ePI)

Expert Panels for Medical Devices (EXPAMED)

To be onboarded:
Union Product Database, eSubmissions, eCTD v4.0

Monitoring

Regulatory Procedure Management for Monitoring

- GxP Inspections
- Parallel Distribution
- Marketing Status

Extended Mandate

- Shortages of Medicines
- Shortages of Medical Devices

To be onboarded

- Signal and Safety Analytics
- Veterinary Programme Monitoring Solutions

Current & released products

Related value stream work

Industry engagement

EMA acknowledges and understand requests to provide opinions on prioritisation choices & strategy

Key vehicles to collaborate

Formal engagement

Strategic and operational through Subject Matter Experts & ceremonies (e.g. Quarterly strategic portfolio review, system demos)

Additional meetings

Meetings, webinars and workshops will be set up on topics as required: engagement in a structured way, but not *structural*

Subject Matters Experts' contribution

Structural subject matter expert participation (content contribution)

Supported by consistent outreach and communications on prioritisation and roadmaps

Update on GxP Inspections and Marketing Status

Presented by: **Pedro Pina Ferreira**, Monitoring Value Stream Owner

Inspections Development & Maintenance Status

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Reported Issue	Under Investigation	Design	Development	Expected Release			
				Q2	Q3	Q4	Comments
• Wrong emails to wrong contacts with wrong numbers* • IRIS user guide feedback(1)		***On-Going***				***Expected***	(1) Unrelated to content of IRIS guide but is caused by submission contact management issue (above).
• Access management for deputies*			**On-Going**		***Expected***		
• Checking to not miss a GMP inspection	**Not an Issue**						However, the EMA will identify any potential issue with the inspections and proactively address the issue.
• Ability to download IRIS GMP inspection information	***On-Going***						
• Submission numbers (visible in IRIS) are different from the GMP Inspection references (in email)				**Delivered**			Submission numbers were removed from the notification email.
• Service Desk response time				**Improved**			Service Desk response time has been reduced. If the issue is related to the content of the inspection case, reply to inspection notification email (feedback).
• GVP pre-go-live industry demo				**Demo on 30th June**			Wide range of industry representatives attending the demo.
• GMP inspections feedback							GMP experience was taken into account for GCP and GVP, no major issues upon go-live.

(*) : Please check IRIS Forum for updates (release dates, information) and latest post questions.

Update on Marketing Status

Status as of 22 June 2022

Resolved

- The problems experienced with the bulk upload have been resolved.
- A communication was sent to all MAHs in April to inform on the progress and actions taken and a subsequent communication was posted in the IRIS Forum in May.

In Progress

- 1024 CAPs have had at least one reporting for one presentation in at least one Member state. This is 78% of all CAPs.
- We will review all points raised by Industry and update the guidance and questions and answers in the Forum, as required.
- Work is still ongoing to solve a remaining issue with new products/presentations that are not visible in IRIS.

  Workaround : For now it needs manual intervention, so MAHs are advised to raise a Service Desk ticket if the product/presentation is not visible for reporting.

  Final Solution : Q3.

Brief update on DADI UAT

Presented by: **Karl Hamilton**, Product Lifecycle Management Value Stream Owner

Human Variations Form Timeline

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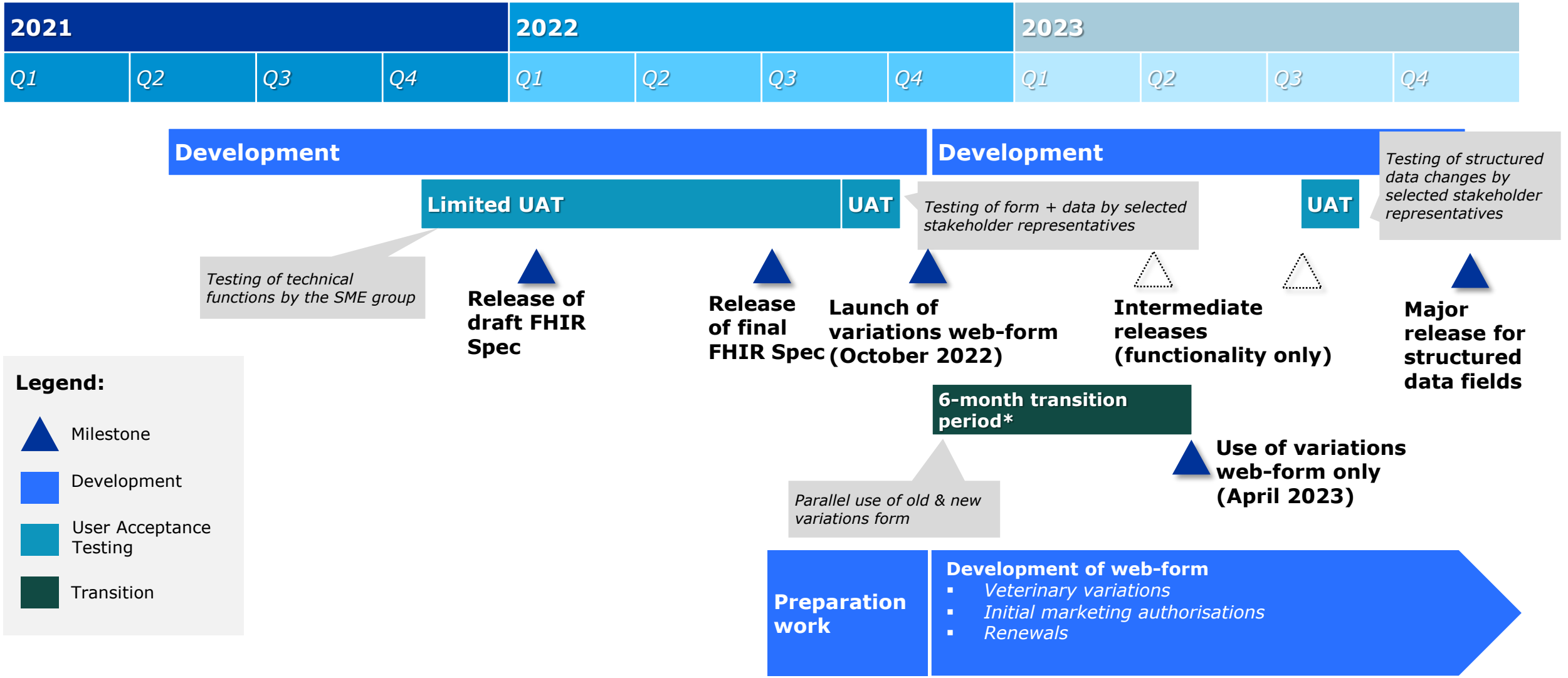
* Correct as of 21 June 2022



* *Any extension to transition periods to be agreed through consultation*
** *Data cleansing is not part of this timeline as it is not a precondition for the use of H Var form at go-live*

DADI Beta UAT Timeline

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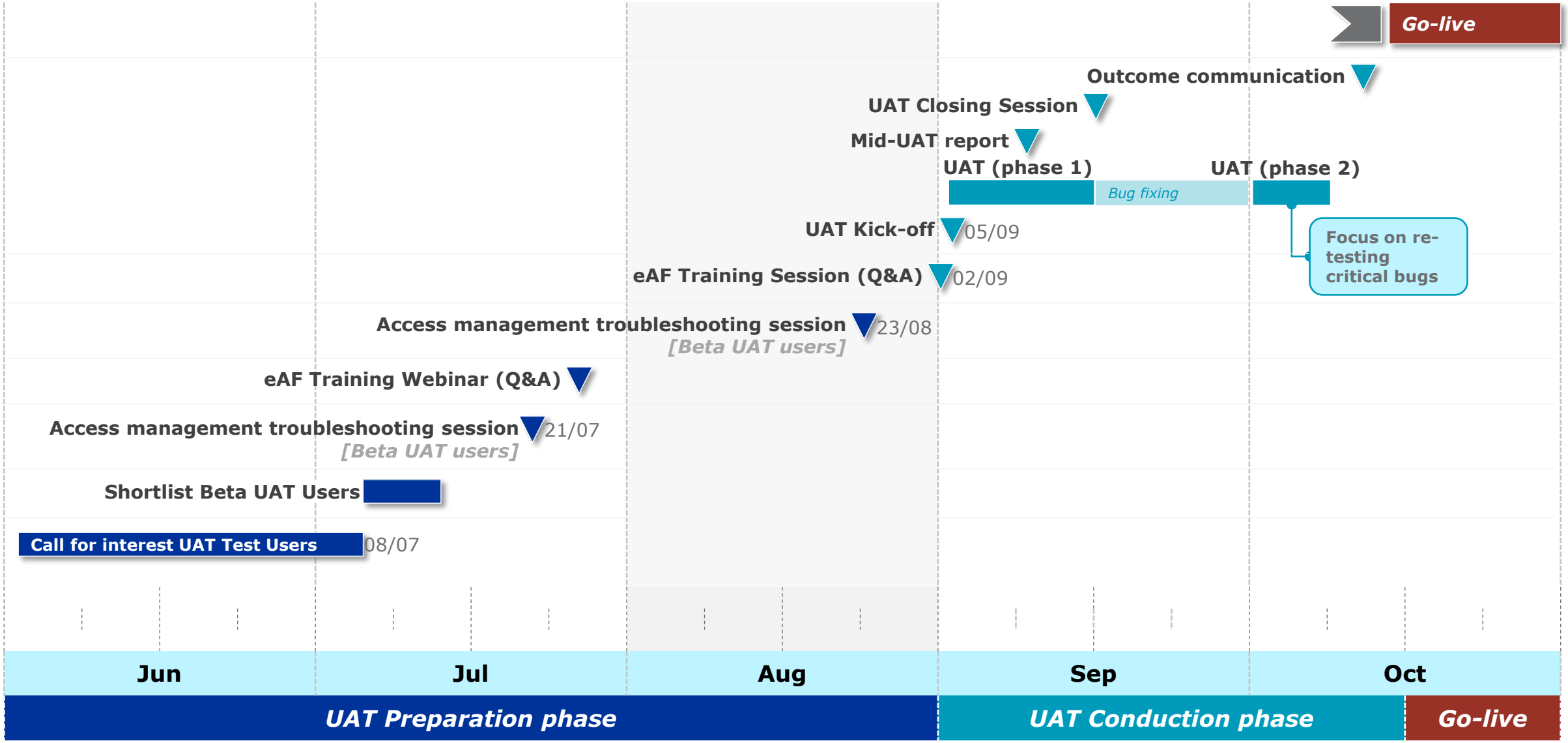
* Correct as of 21 June 2022



Questions and feedback

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