Medicines & Healthcare products
Regulatory Agency

Clinical Trials - Information Pack

How to submit to the MHRA in a EU no-deal scenario

CPRD NIBSC MHRA

Overview

In the event of a no deal EU exit, all new commercial and non-commercial clinical trials will need to be submitted via MHRA Submissions.

Up until the Friday, 29 March, users will be able to submit applications for Clinical Trial Authorisations (including Initial Applications, Substantial Amendments, End of Trial Notifications and Developmental Safety Update Reports (DSURs)) via CESP. In a no deal EU exit, users will need to submit their applications via MHRA Submissions.

You will still be required to obtain and use a EudraCT number as your reference number: you will continue to get this number from the EudraCT website.

All users requiring access to Clinical Trials submissions will need to register for access to MHRA Submissions.

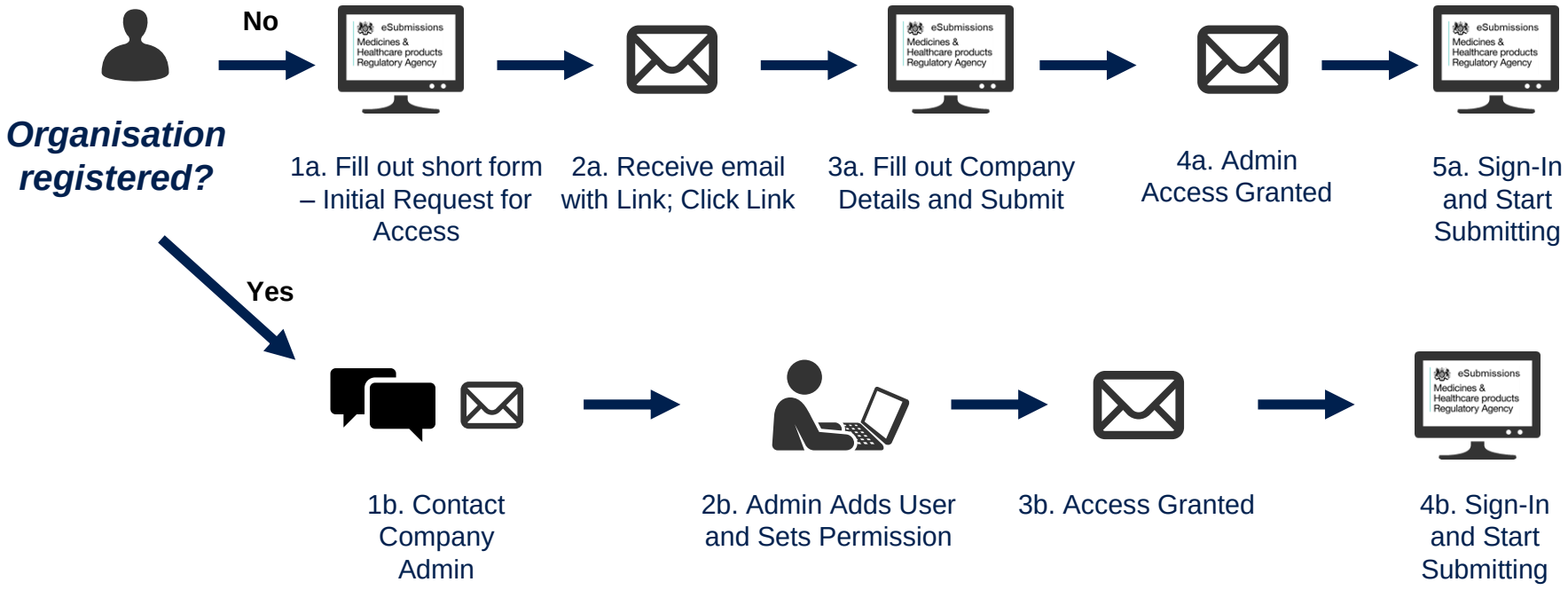
https://www.gov.uk/guidance/making-submissions-to-the-mhra-in-a-no-deal-scenario

Whilst SUSARs can continue to be submitted via the MHRA eSUSAR portal, there will also be other solutions to replace EVWEB and Eudravigilance Gateway.

Overview

- The aim of this ‘Information Pack’ is to provide answers to the following questions for both commercial and non-commercial clinical trials applicants:
  - How can I register to use MHRA Submissions?
  - How do I enable other users in my organisation to submit via MHRA Submissions?
  - How should I be submitting Clinical Trials submissions via MHRA Submissions?
  - How do I submit Developmental Safety Update Reports (DSURs) via the new system?
  - Can we continue to use any of the existing systems?
  - When are the new systems going to be ready to use?

MHRA Submissions – User Access Management



The Company Administrator is delegated responsibility for adding and maintaining further users, including additional administrators and 3rd party consultants.

The first applicant to register for an organisation will be assigned as the initial Company Administrator. See slide 6 for further information about user management and the role of the Company Administrator.

Register with MHRA Submissions

All users requiring access to Clinical Trials submissions will need to register for access to the MHRA Submissions portal.

- Please read the guidance in the ‘Gaining Access to MHRA Submissions’ webpage before starting the process of gaining access:

https://www.gov.uk/guidance/making-submissions-to-the-mhra-in-a-no-deal-scenario

- A user reference guide can be found here: Gaining Access to MHRA Submissions
  - *NOTE: Clinical Trials – Non-commercial users will need to select ‘Non-commercial’ under ‘Organisation type’ in Stage 4 of the user reference guide.*

- We hosted a webinar with demonstrations for ‘User Access Management’ which is also available here:

https://www.gov.uk/government/publications/how-to-make-regulatory-medicines-submissions-to-the-mhra-if-the-uk-leaves-the-eu-with-no-deal

- Registration for MHRA Submissions is available now.

User Management –clinical trial applicants

If you are the first person to register for an organisation, you will become the initial ‘Company Administrator’.

This means that you are able to add other colleagues as either company administrator or as users.

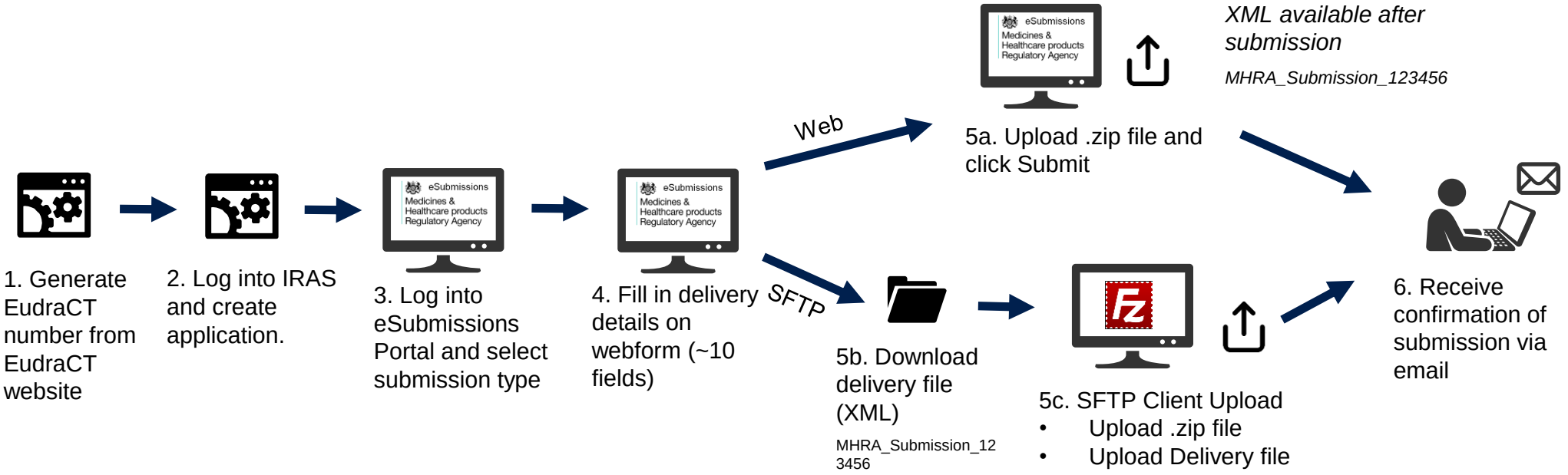
All company administrators will be able to add and remove users and company administrators. They will also have a record of submissions made for that organisation.

Carefully consider who in your organisation is best placed to be this initial company administrator. For example, it is recommended that a company administrator works in your Regulatory Affairs department (for commercial sponsors) or in the R&D department or Clinical Trials Unit (for non-commercial sponsors).

If you attempt to register for the MHRA Submissions portal and an account is already set up, you will be told to contact your company administrator. Please check with your Regulatory Affairs, R&D Department or Clinical Trials Unit if you are not aware of who this is.

For technical issues or other support queries, please email submissions@mhra.gov.uk.

CT Submissions – Commercial and Non-Commercial User Journey



Submission Type	Route into MHRA	Submission Format	Associated File upload	XML Creation?	Download Required?	Comments
CT	eSubmissions Portal SFTP	• 1 webform, ~10 fields • SFTP	.zip file	Yes	XML needed by user	Note – SFTP users will need to create the delivery file (XML) and then submit via SFTP

Making submissions

For sponsors looking to submit Clinical Trial submissions, this can be accessed under the ‘Human Medicines’ tile of MHRA Submissions.

Further detailed guidance on submitting will be published towards the end of March.

Please note, the Developmental Safety Update Report (DSUR) will also be submitted via the ‘Human Medicines’ tile.

SUSAR reporting

Guidance and the link to register for ICSR Submissions will be published on Monday, 11 March. Clinical Trial sponsors currently submitting via the Eudravigilance Gateway will be able to register and test to use the new MHRA Gateway.

The eSUSAR portal will continue to be available to submit SUSARs post Friday, 29 March.

A recording of the webinar: Vigilance – MHRA Gateway and ICSR Submissions is available below.

https://mhra.sharefile.com/share/view/s27ae84cf5ad4aa3a

Please note: Gateway users will first need to gain access to MHRA Submissions as this is where the Gateway registration steps are performed.

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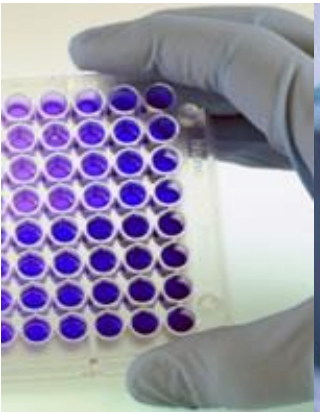
If you have more questions regarding registration for MHRA Submissions, please email submissions@mhra.gov.uk.



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