Medicines & Healthcare products
Regulatory Agency

Submitting via MHRA Submissions portal

CPRD NIBSC MHRA

Agenda

Item
Intro
The MHRA Submissions homepage
Submitting e-cigarettes
Submitting via Human Medicines
Submitting PSURS
Submitting PIPs
Next Steps

Introductions

This webinar

- The requirements and proposals we are presenting are drafts, and do not at this stage represent Government policy.
- This session is to provide information and can be shared with colleagues.
- This Webinar is to showcase and answer questions on the technical process of submitting information.

Webinar purpose

This webinar will focus on MHRA Submissions

- Providing an overview of MHRA Submissions Homepage
- How to raise a query from the MHRA Submissions Homepage and find support documents
- Submitting marketing authorisation and Clinical trial applications via the Human Medicines tile
- Submitting PSURs
- Submitting PIPs
- Submitting e-cigarette notifications
- Next steps

1. MHRA Submissions Homepage

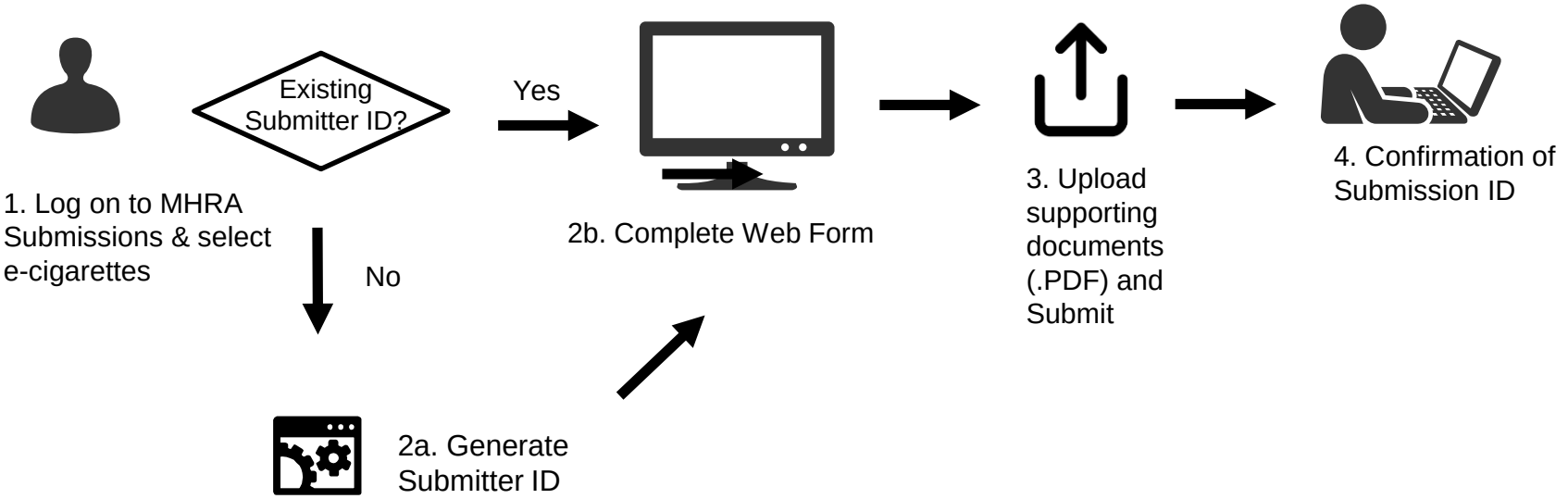
MHRA Submissions overview

Video demo:

MHRA Submission Homepage

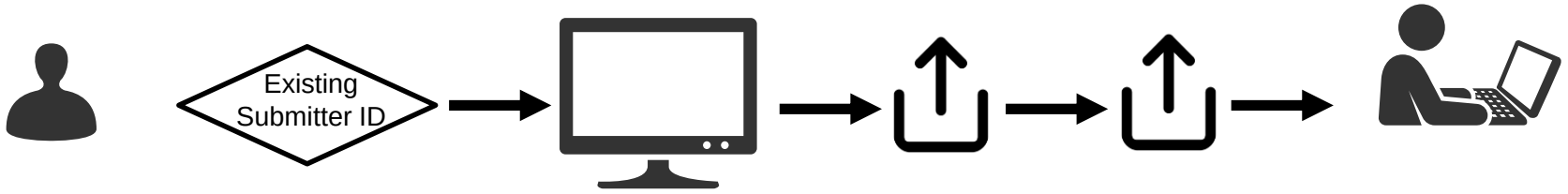
2. e-cigarette notifications

E-cigarette Submission– Industry User Journey



Submission Type	Route into MHRA	Submission Format	Associated File upload	XML Creation?
E-cigarette	MHRA Submissions	Webform, edit previously submitted data	attachments	No

E-cigarette Bulk Submissions– Industry User Journey



1. Log on to MHRA Submissions and select e-cigarettes

2. Complete Web Form

3. Upload XML files

4. Upload supporting documents (.PDF) and Submit

5. Confirmation of submitter ID

Submission Type	Route into MHRA	Submission Format	Associated File upload	XML Creation?
E-cigarettes – Bulk	MHRA Submissions	Webform related to submitter details	attachments	No

E-cigarette notifications

Video demo

Making an e-cigarette submission

Making a Bulk Submission

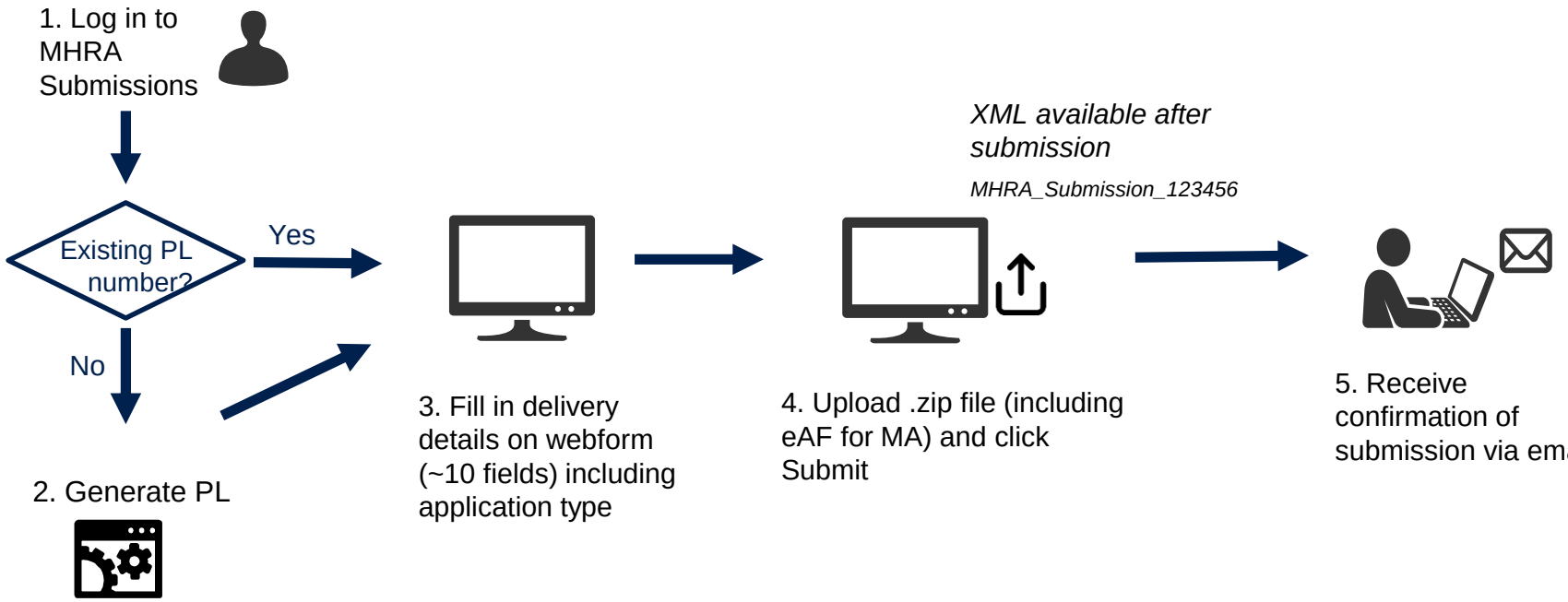
3. Human Medicines

What applications will be sent via Human Medicines?

Regulatory Activity
Initial Marketing Authorisation Application
CAP Grandfathering Full Initiating Sequence
CAP Grandfathering Full Initiating Sequence Incorporating Change of Ownership (COA)
CAP Grandfathering Minimal Initiating Sequence
CAP Grandfathering Minimal Initiating Sequence Incorporating Change of Ownership (COA)
Variation Type IA
Variation Type IB
Variation Type II
Renewal (yearly or 5-yearly)
Information Update
Active Substance Master File
Plasma Master File
Paediatric submission, Article 29
Paediatric submission, Article 46
Full PIQ assessment - Notification 61(3)
Change of Ownership Application (COA)

Ownership Application (COA) - EU to UK MAH
Article 23a/24 Sunset Clause Notification
Withdrawal during assessment or withdrawal of a marketing authorisation
Clinical Trial
Parallel Import (PLPI) Variation
Parallel Import (PLPI) Initial
Parallel Import (PLPI) Renewal
Targeted Assessment
Baseline Submission
Development Safety Update Reports
BROMI Self Certification - Notification 61(3)
Notified Body Designation
Homeopathic National Rules (NR)
Homeopathic MP application (HR)
Herbal MP application (THR)
Article 45 - Paediatric submission
Early Access to Medicines UK
Export Certificates
CCC Procedure UK

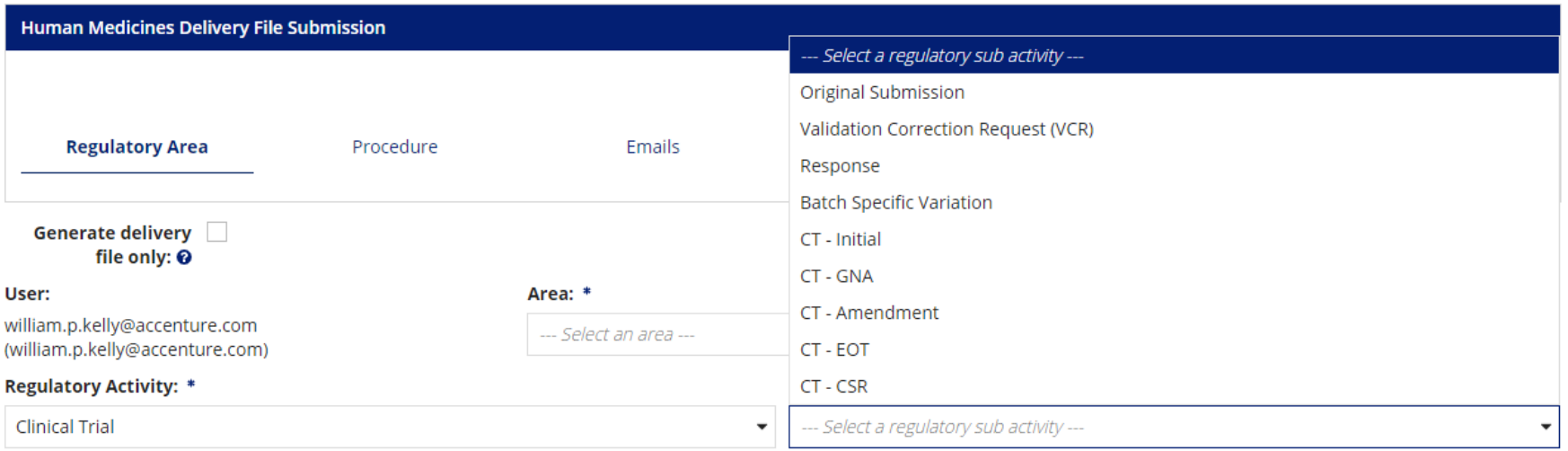
Human Medicines– Industry User Journey



Submission Type	Route into MHRA	Submission Format	Associated File upload	XML Creation?	Comments
All types outlined in previous slide	MHRA Submissions	• 1 webform, ~10 fields	.zip file (e.g. MA - eCTD format)	Yes	Note – Uploading large files as outlined here is the preferred method. Please inform us if you have a requirement to submit via SFTP from Day 1.

Clinical Trial applications

All clinical trial applications types will be submitted via this Human Medicines tile.



Please note - For all new clinical trial submissions post 1st Jan 2021 your Application Form (PDF and XML) should be generated in IRAS (https://www.myresearchproject.org.uk/). If you have already created and downloaded an Annex 1 form (PDF and XML) in EudraCT before the end of the year, this will be accepted. It will still be required to obtain and use a EudraCT Number as your trial reference number.

Human Medicines submissions

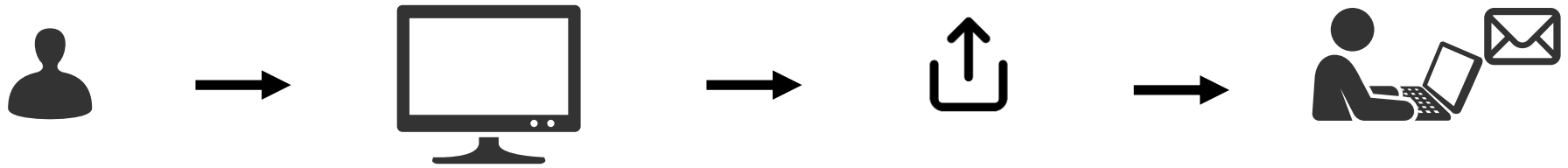
Video demos

Generating a PL Number

Making a human medicines application

4. PSUR

PSUR Submissions – Industry User Journey



1. Log on to MHRA Submissions. Go to PSUR tile

2. Complete Web Form (<10 fields)

3. Upload PSUR . Click submit

4. Receive email confirmation of submission

Submission Type	Route into MHRA	Submission Format	Associated File upload	XML Creation?	Download copy of Application Required?
PSUR	MHRA Submissions	1 webform, <10 fields	Zip/pdf or word	No	No

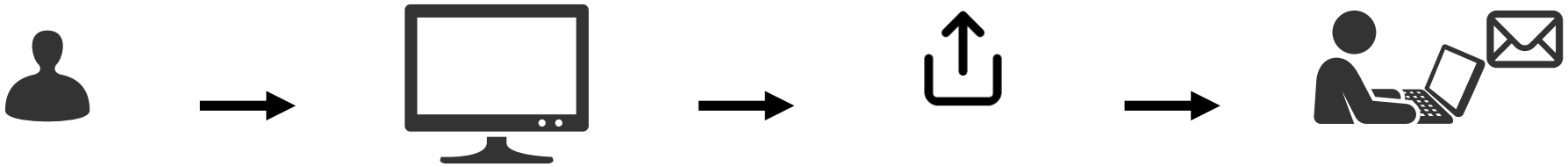
PSUR submissions

Video demo

Making a PSUR submission

5. PIPs

PIPs Submissions – Industry User Journey



1. Log on to MHRA Submissions and select PIPs

2. Complete relevant Web Forms

3. Upload supporting documents (.PDF, .zip, unstructured documents). Click submit

4. Receive email confirmation of submission and notification of UK-PIP number

Submission Type	Route into MHRA	Submission Format	Associated File upload	XML Creation?	Download copy of Application Required?
PIPs	MHRA Submissions	5 webforms available	.PDF file, .zip file, unstructured documents	No	No

PIPs submissions

Video demo

Making a PiP Submission

Next Steps:

- Ensure that your organisation completes the user access steps for MHRA Submissions prior to 31st December 2020.

- These steps and guidance are found here:

https://www.gov.uk/guidance/registering-to-make-submissions-to-the-mhra-from-1-january-2021

- For any support please contact submissions@mhra.gov.uk