EUDAMED

Notified Body experience

28 April 2022

EUDAMED Playground NB & Certificates Module

1. EUDAMED Playground v 1.1
   - NBs allowed to comment 06-30 April 2021

2. EUDAMED Playground v 1.2
   - v 1.2 open 29 July 2021
   - v 1.2.1 open 19 Aug 2021
   - Feedback prior to 05 Sept 2021

3. EUDAMED Playground v 3.0
   - NBs allowed to comment 08 Apr – 10 May 2022

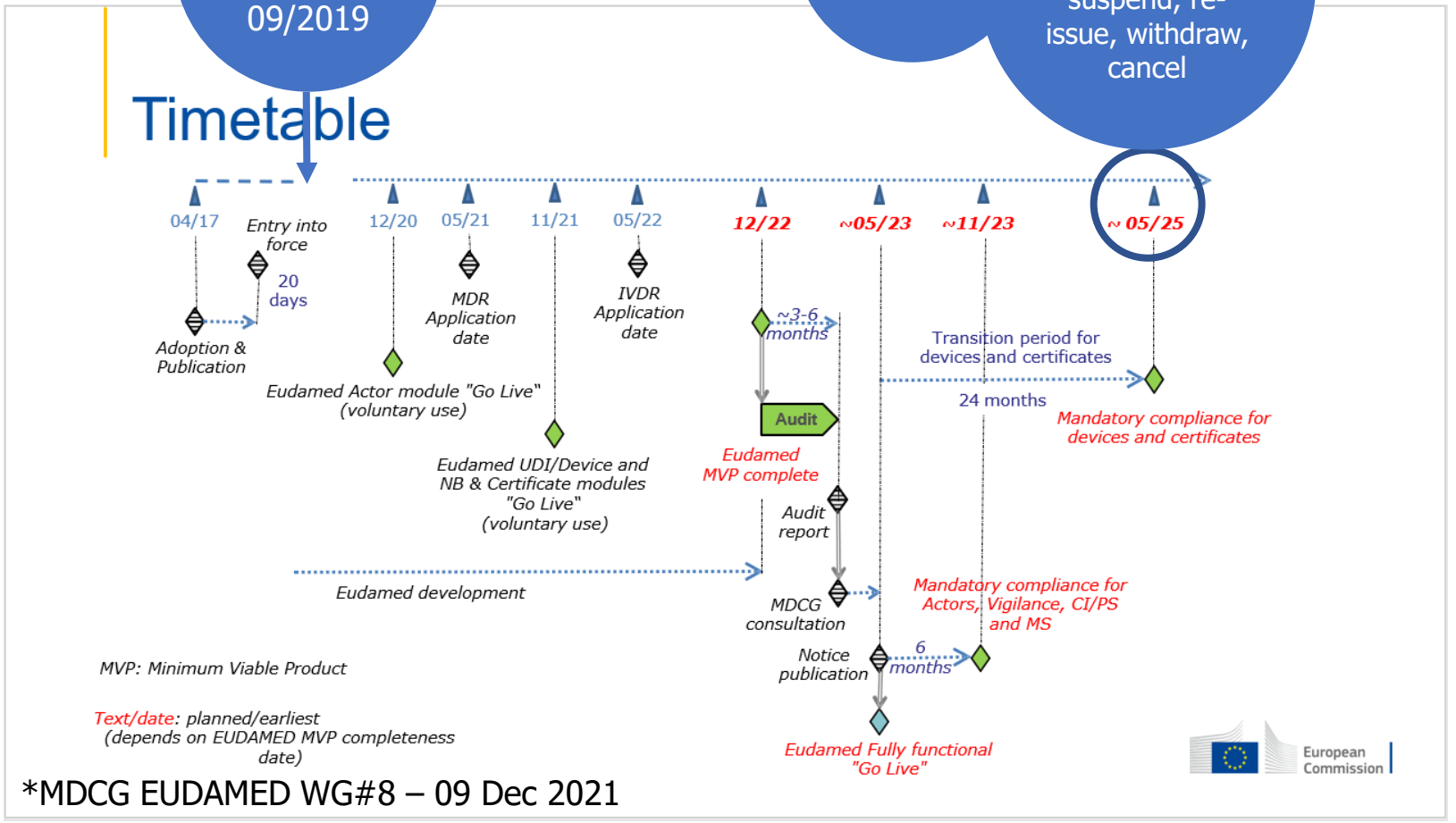
- 100% manual entry of information will be required for more than two years. Machine to machine communication is not considered part of the 'minimum viable product.'
- 'undo' or 'discard' function to correct errors was not considered part of the 'minimum viable product.'
- Management of CECP – many open questions. CECP may continue through an alternative means – CIRCABC.
- Management of (PECP) Class D with no CS – may never be programmed in EUDAMED. CIRCABC for ever?
- Management of SS(C)P – many open questions.
- Management of PSUR – Vigilance Module of EUDAMED Playground, only one PSUR uploaded. Anticipate similar challenges to management of SS(C)P.
- Management of refusals and withdrawals – requirement for SRN & Basic UDI-DI. Can Basic UDI-DI be removed as a mandatory field? Refusal / withdrawal may continue through an alternative means – CIRCABC?
- Commission – 'no time for training of NBs.'

EUDAMED Production NB & Certificates Module

1st NB certificate issued 09/2019

>5 years of certificates

issue, amend, supplement, restrict, suspend, re-issue, withdraw, cancel

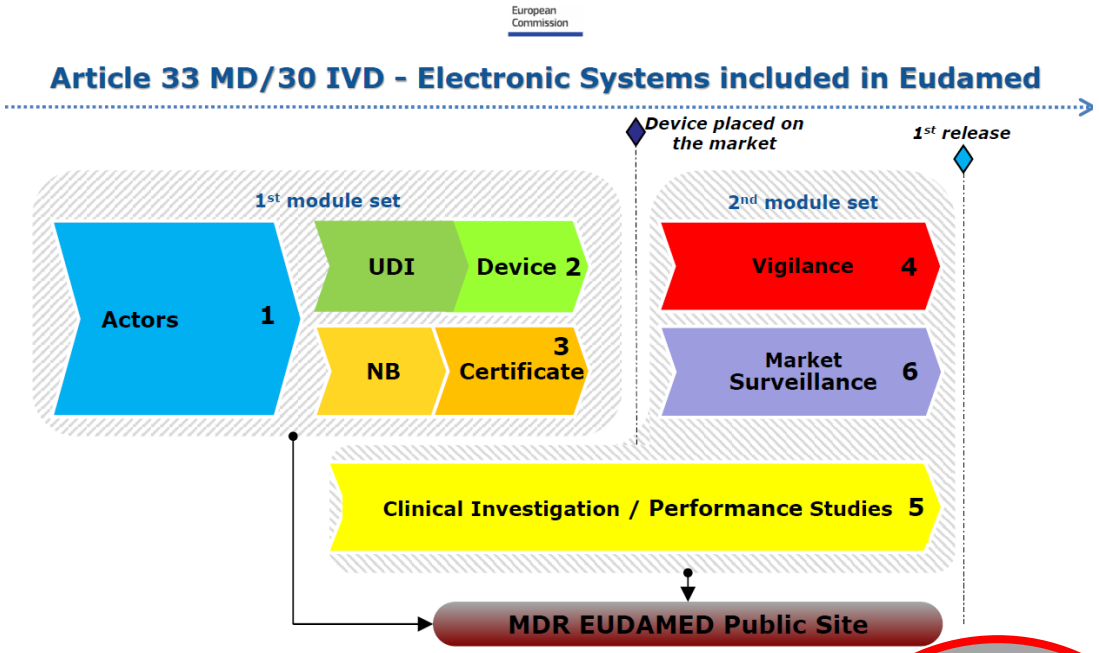


*MDCG EUDAMED WG#8 – 09 Dec 2021

Suggestion: One time synchronisation at time of issue / re-issue

EUDAMED Production

Clinical Investigations / Performance Studies



Suggestion: Allow NBs visibility of CI/PS Module

Periodic Safety Update Report

Article 86 MDR / Article 81 IVDR

Throughout the lifetime of the device concerned, that PSUR shall set out:

a) the conclusions of the benefit-risk determination;

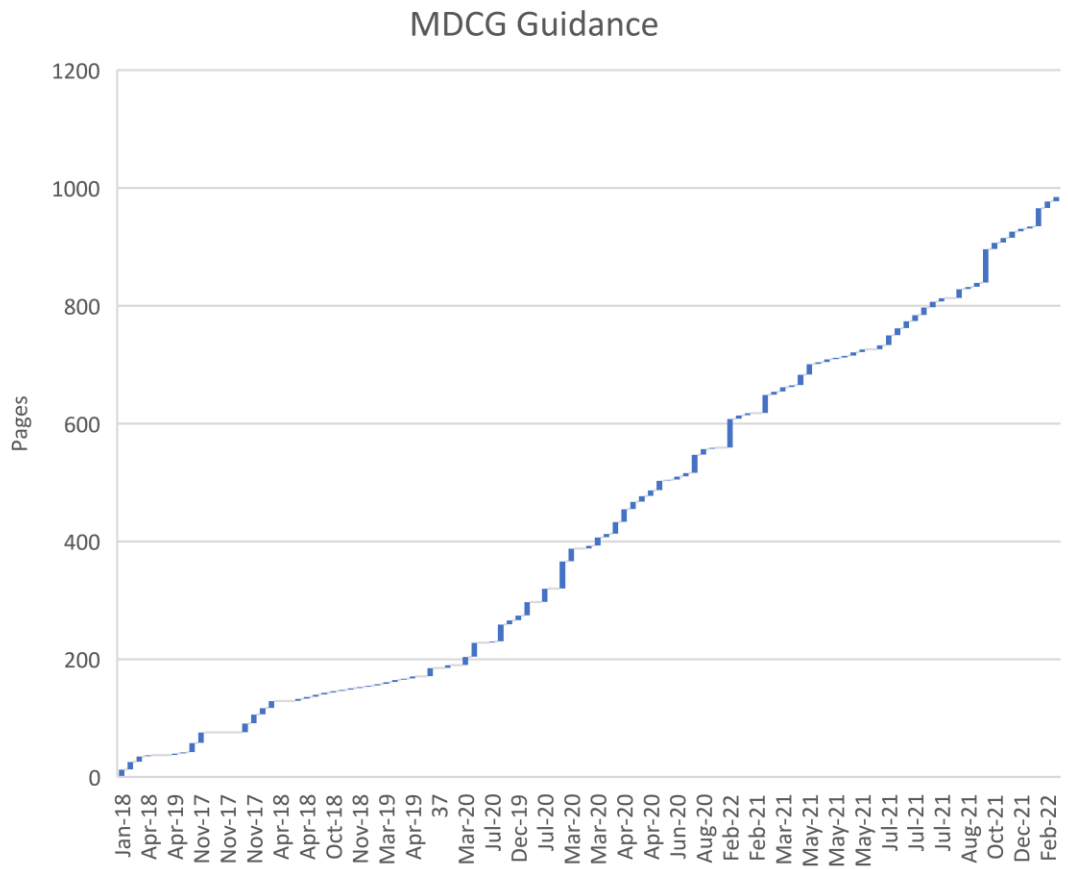
b) the main findings of the PMCF; and

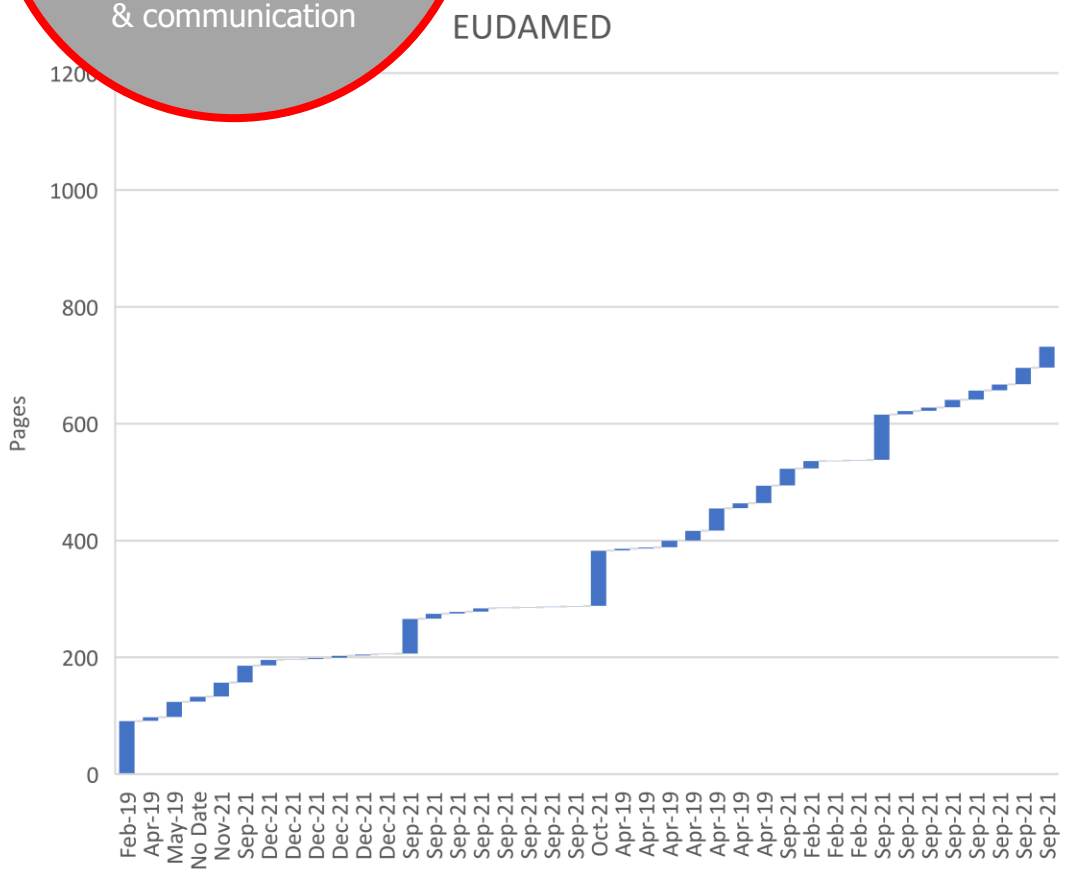
c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

***The notified body shall review the report and add its evaluation to that electronic system with details of any action taken.**

Guidance Documents

Suggestion:
- 4 months gap analysis
- 4 months update forms, procedures, IT systems
- 4 months training & communication





Questions & Answers