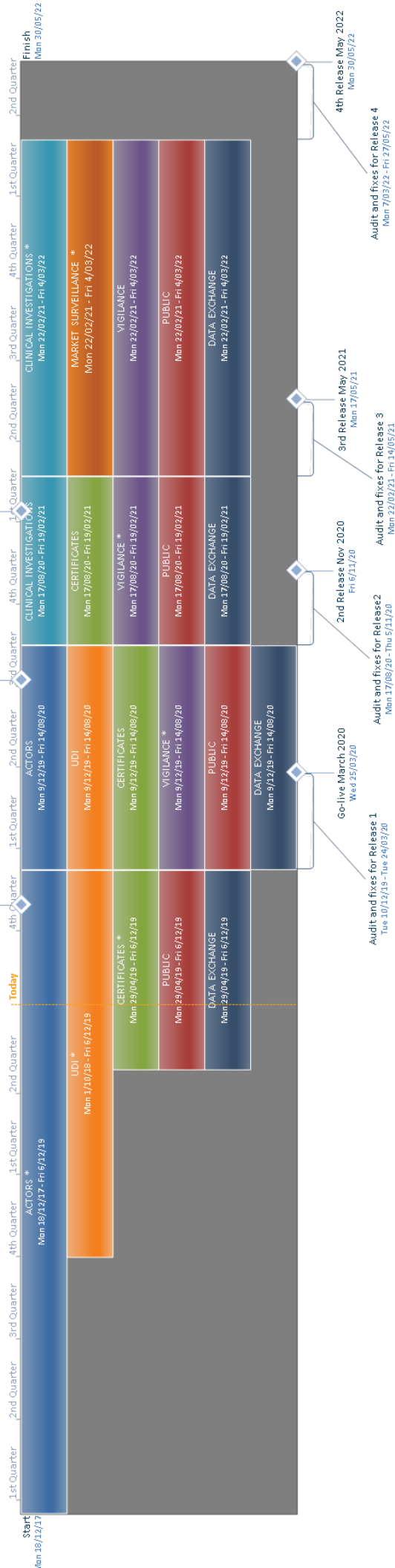# Eudamed Roadmap

15th July 2019

<u>Introduction</u>

This document presents the Eudamed High Level Roadmap as agreed between R3 and D4, with the main IT modules, milestones and the assumptions for a successful execution of the project.

OUT OF SCOPE

The High Level Roadmap is based on the current knowledge of complexity of the requirements of the last modules to be released, namely, Vigilance, Market Surveillance, and Clinical Investigations.

High Level Roadmap

The modules marked with an asterisk will be the main modules developed, in terms of functionality, of a particular release.

Start
Mon 18/12/17

Finish
Mon 30/05/22

ACTORS *
Mon 18/12/17 - Fri 6/12/19

UDI *
Mon 1/10/18 - Fri 6/12/19

CERTIFICATES *
Mon 29/04/19 - Fri 6/12/19

PUBLIC
Mon 29/04/19 - Fri 6/12/19

DATA EXCHANGE
Mon 29/04/19 - Fri 6/12/19

Today

ACTORS
Mon 9/12/19 - Fri 14/08/20

UDI
Mon 9/12/19 - Fri 14/08/20

CERTIFICATES
Mon 9/12/19 - Fri 14/08/20

VIGILANCE *
Mon 9/12/19 - Fri 14/08/20

PUBLIC
Mon 9/12/19 - Fri 14/08/20

DATA EXCHANGE
Mon 9/12/19 - Fri 14/08/20

CLINICAL INVESTIGATIONS
Mon 17/08/20 - Fri 19/02/21

CERTIFICATES
Mon 17/08/20 - Fri 19/02/21

VIGILANCE *
Mon 17/08/20 - Fri 19/02/21

PUBLIC
Mon 17/08/20 - Fri 19/02/21

DATA EXCHANGE
Mon 17/08/20 - Fri 19/02/21

CLINICAL INVESTIGATIONS *
Mon 22/02/21 - Fri 4/03/22

MARKET SURVEILLANCE *
Mon 22/02/21 - Fri 4/03/22

VIGILANCE
Mon 22/02/21 - Fri 4/03/22

PUBLIC
Mon 22/02/21 - Fri 4/03/22

DATA EXCHANGE
Mon 22/02/21 - Fri 4/03/22

Deadline for stable
requirements for Release 2
Mon 28/10/19

Deadline for stable
requirements for Release 3
Mon 6/07/20

Deadline for stable
requirements for Release 4
Mon 11/01/21

Audit and fixes for Release 1
Tue 10/12/19 - Tue 24/03/20

Go-live March 2020
Wed 25/03/20

Audit and fixes for Release2
Mon 17/08/20 - Thu 5/11/20

2nd Release Nov 2020
Fri 6/11/20

Audit and fixes for Release 3
Mon 22/02/21 - Fri 14/05/21

3rd Release May 2021
Mon 17/05/21

Audit and fixes for Release 4
Mon 7/03/22 - Fri 27/05/22

4th Release May 2022
Mon 30/05/22

This roadmap does not reflect the work performed on the analysis of business requirements which was started in 2016 and which will continue throughout the project.

OUT OF SCOPE
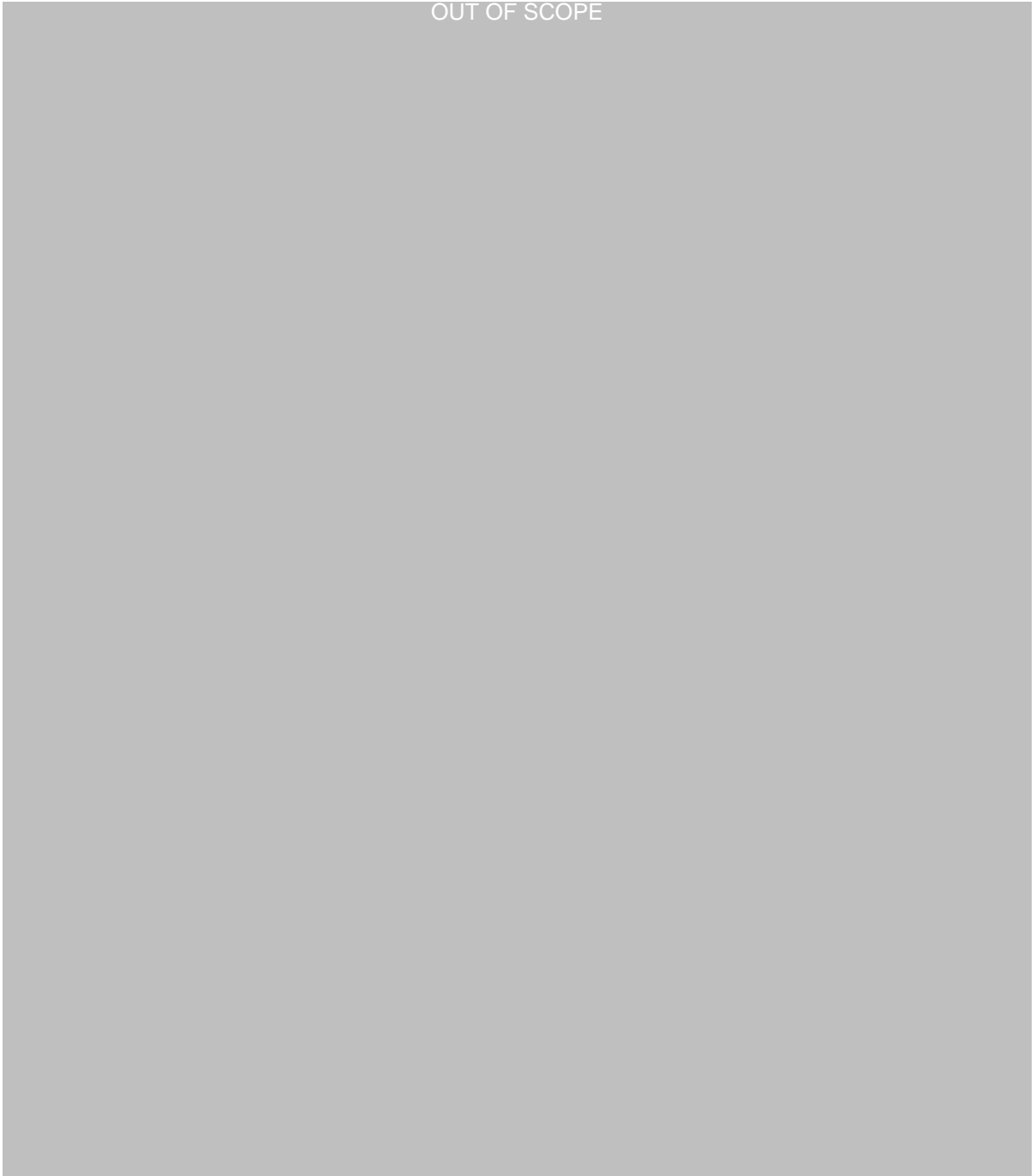
<u>Resources</u>

- Both Units recognize that delivering the agreed Roadmap will require additional resources in R3 from mid-2020, in particular for the delivery of releases 3 and 4. This planning brings the final delivery date to May 2022, 6 months earlier than the planning proposed to the MDCG (Medical Device Coordination Group) recently

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