



EUDAMED Project: Understanding the Essentials

ACKOMAS WEBINARS 1/8

Q1-2025 – THURSDAY, JANUARY 23 2025

ENGLISH VERSION



 Jean-Philippe Joubert

Email: jpjoubert@ackomas.com

www.ackomas.com

ACKOMAS is a software publisher

- Expert in Regulatory Compliance
- Dedicated to the Medical Device industry
- M2M solution for EUDAMED, operational since 2021, and
- for other existing (GUDID) and upcoming regulatory databases

ACKOMAS is a partner of

- MEDTECH Europe
- GS1Healthcare
- ISPE (international Society for Pharmaceutical Engineering)

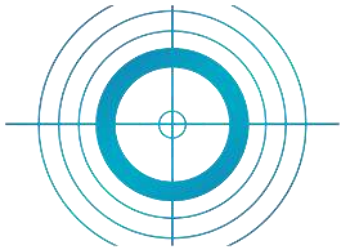
Regular and Operational Exchanges among us



#	List of Ackomas Webinars for Q1-2025	Dates
1	EUDAMED Project : Understanding the Essentials	Jan 23, 25 3pm
2	Manually Entering Your Data into EUDAMED?	Jan 30, 25 3pm
3	Uploading XML files into EUDAMED?	Feb 06, 25 3pm
4	Processing EUDAMED Updates with an M2M Solution	Feb 13, 25 3pm
5	Who is Interested in EUDAMED within the Company? Who leads?	Feb 20, 25 3pm
6	Global challenges of Regulatory Databases	Feb 27, 25 3pm
7	EUDAMED vs GUDID	Mar 06, 25 3pm
8	EUDAMED Budget: How to Plan & Optimize Your Expenses	Mar 13, 25 3pm

3:00 PM Central European time (CET)

12 months Before the First EUDAMED Deadline



1. Understanding the Challenges of Regulatory Compliance
2. Reviewing the EUDAMED Deadline Schedule
3. Identifying the Various Potential Workstreams of an EUDAMED Project
4. Sequencing an EUDAMED Project for 2025
5. Sharing Some Feedback and Experiences

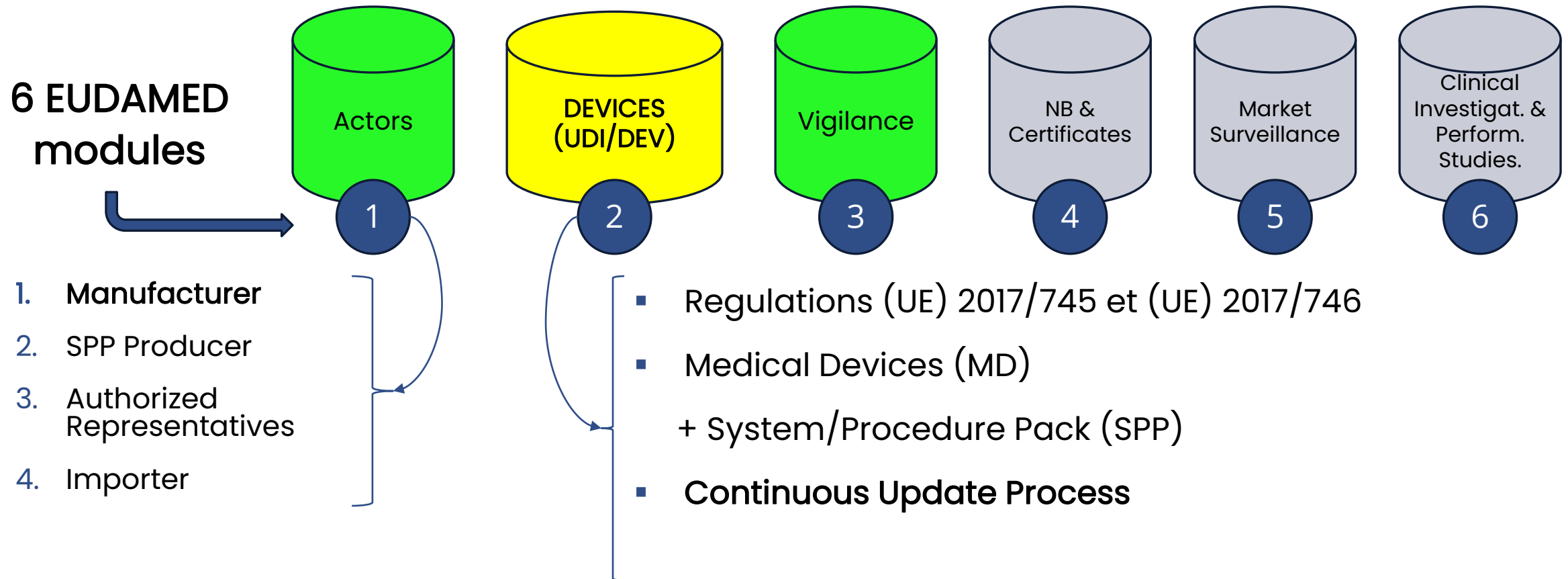
Data as Important as the Medical Device



- **Key Objectives of EUDAMED:**
 1. Enhanced monitoring of the medical device market
 2. Transparency and traceability within the EU

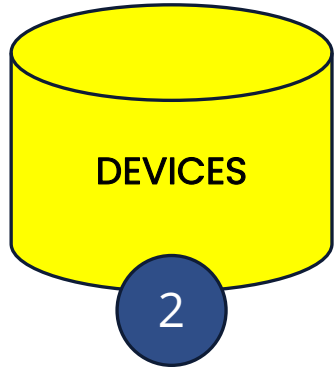
- **Risk of non-compliance: prohibition of commercialization**
(Article 29 §4 of Regulation (EU) 2017/745)

The « DEVICES » module, the Main Workload

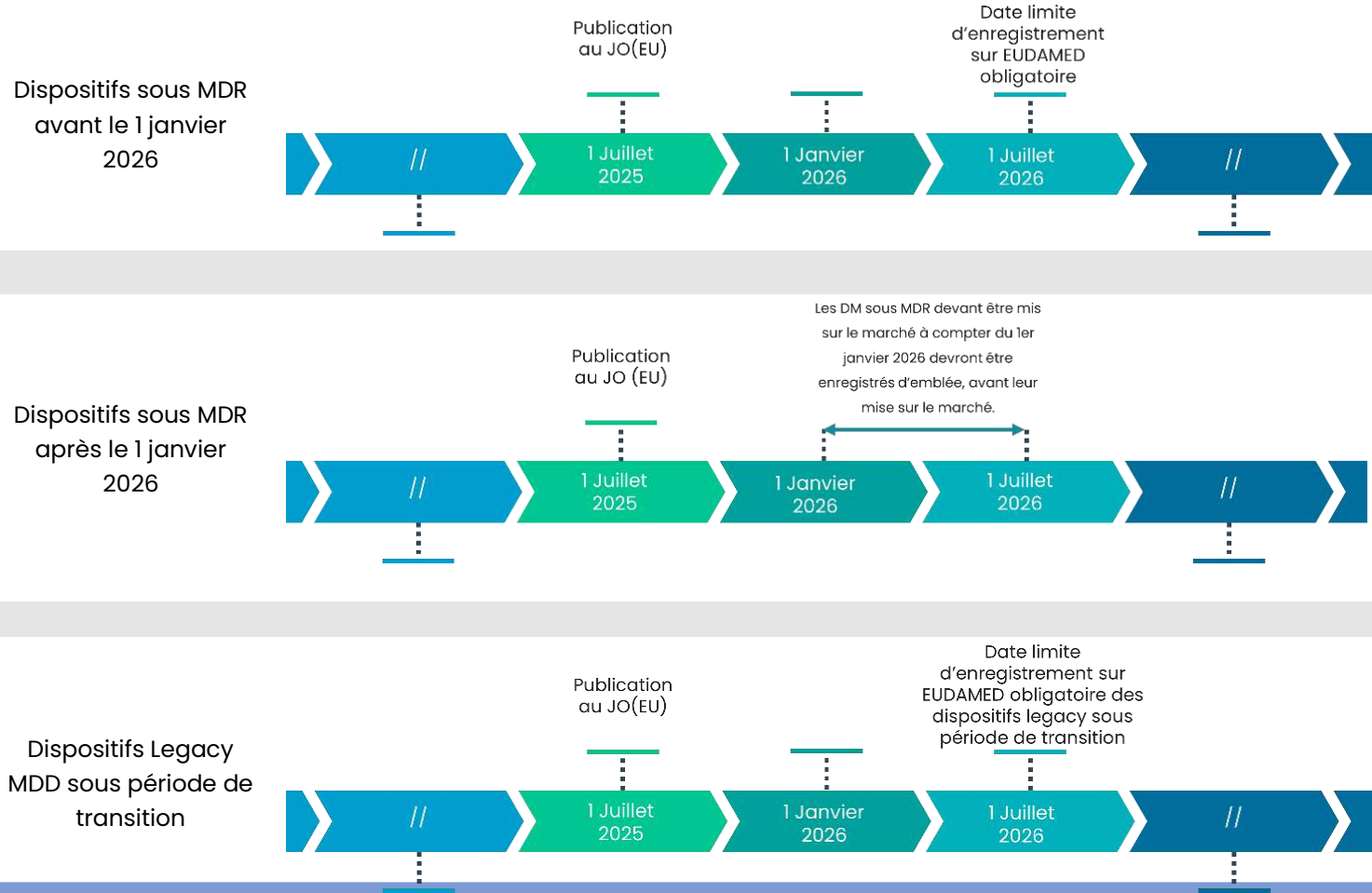


Webinar 1/8 – EUDAMED Project : Understanding the Essentials

Define the Project End Date

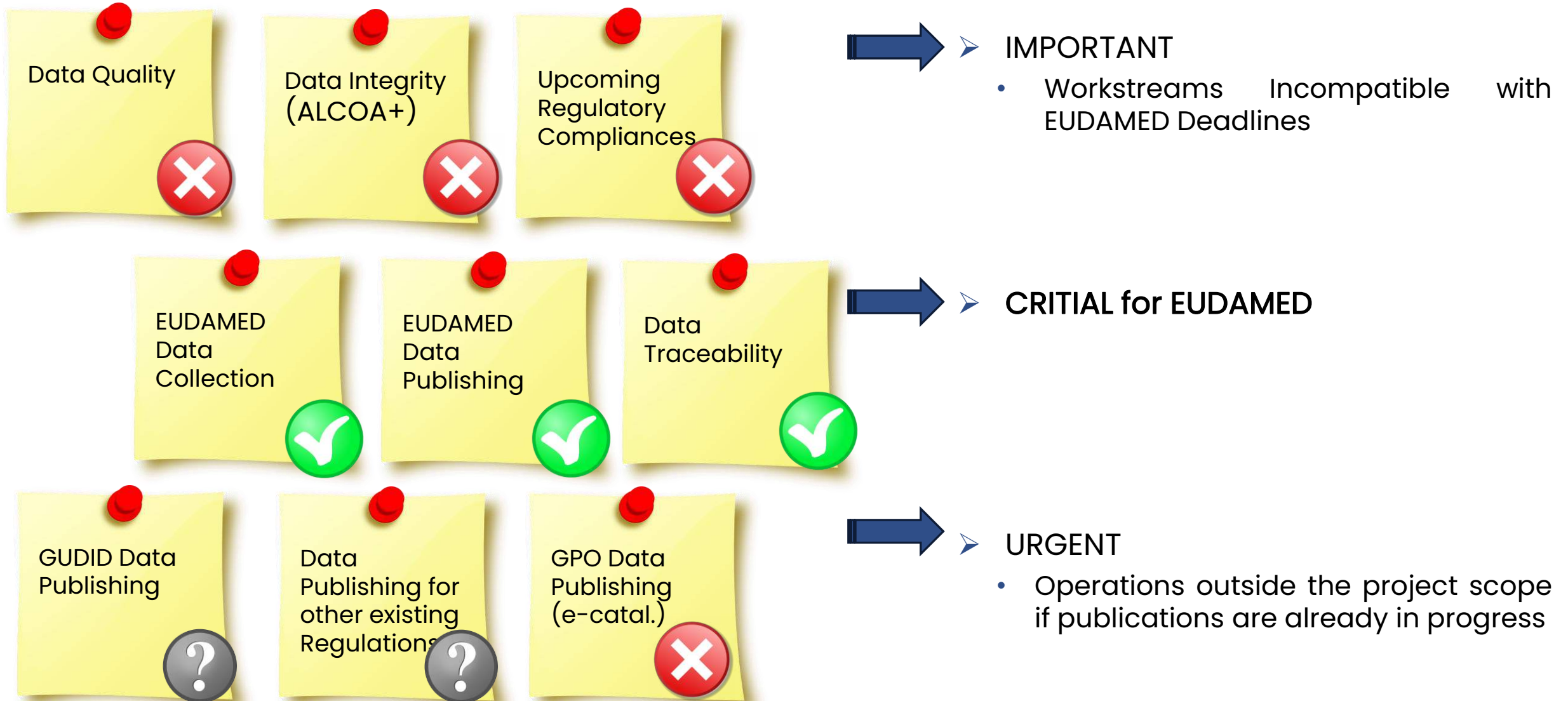


EUDAMED Data Registration Schedule



Webinar 1/8 – EUDAMED Project : Understanding the Essentials

What are the Workstreams for this Project?



Webinar 1/8 – EUDAMED Project : Understanding the Essentials

Key Elements related to the Workstreams Selected for the Project

EUDAMED
Data
Collection



11. Understand the Scope of MDR
12. Define the mandatory EUDAMED Attributes (Company Dictionary)
13. Identify the Source of these Mandatory Data in the Company's IT System
14. Collect the Data

EUDAMED
Data
Publishing



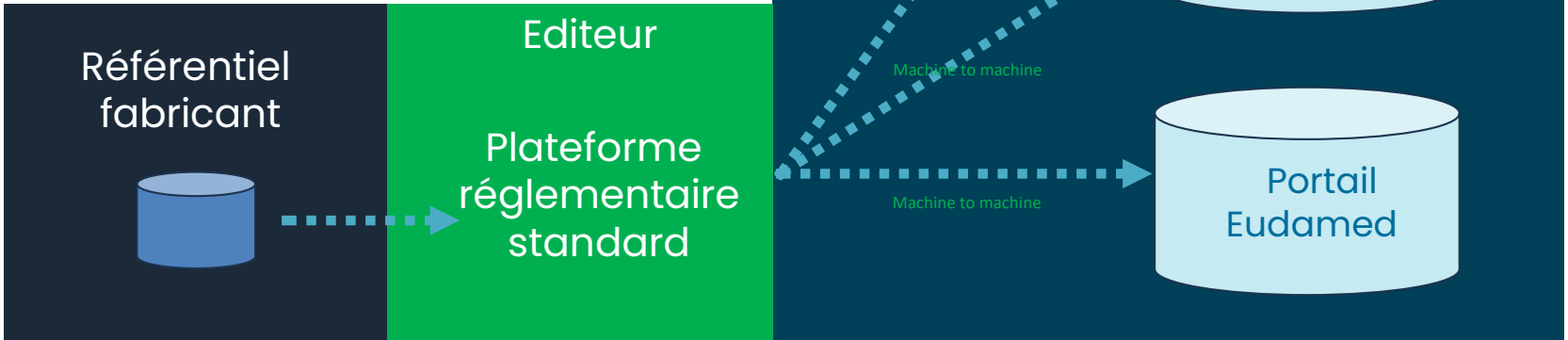
21. Assess the Volume of UDI-DI for EUDAMED
22. Implement an M2M Solution (Ackomas Solution Recommended)
23. Use EUDAMED Excel File (Ackomas Excel File is Simpler)
24. Publish in M2M

Data
Traceabil.

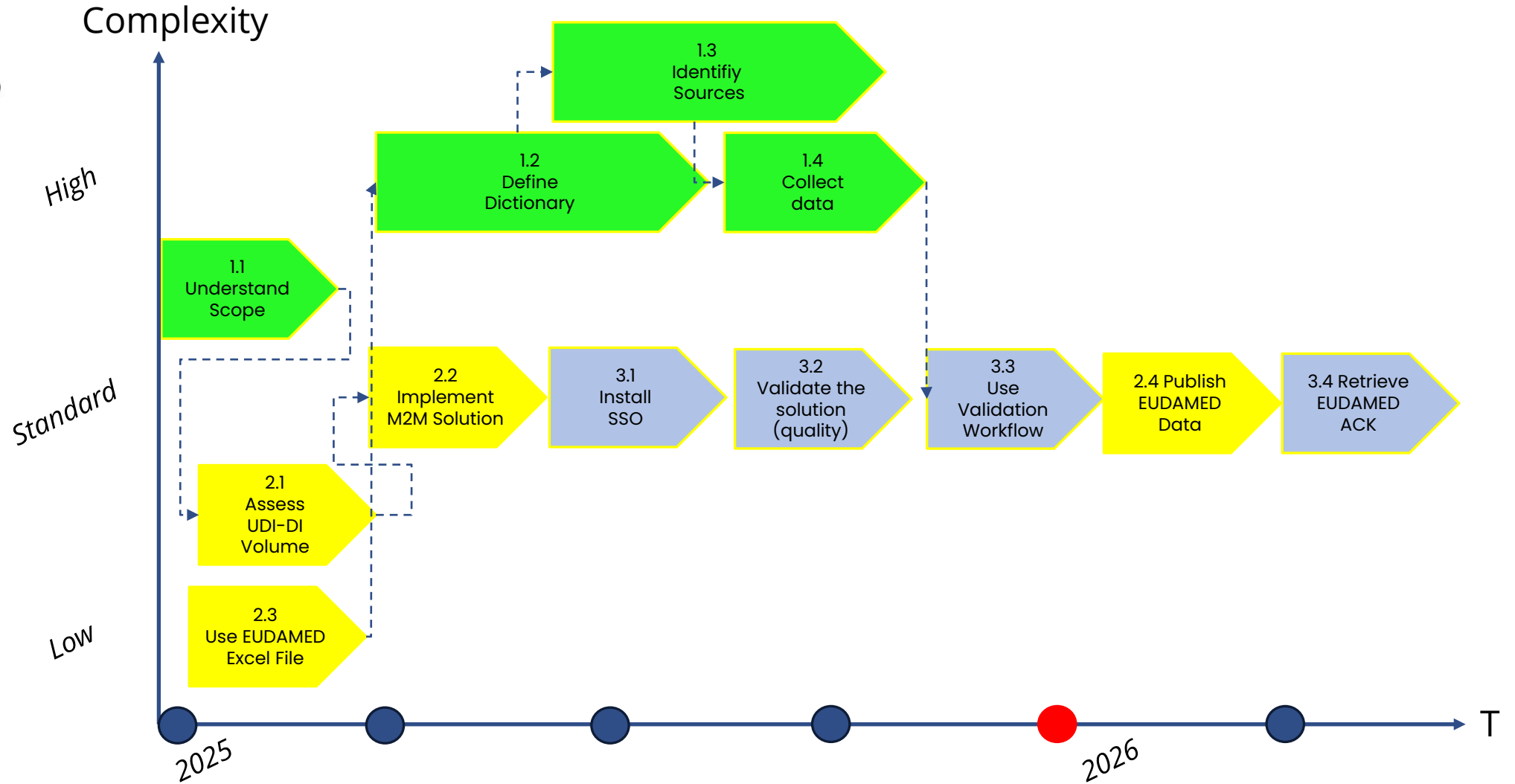


31. Install the SSO
32. Validate the Solution: IQ/OQ/PQ (Ackomas Deliverable / Tests)
33. Use the Validation Workflow
34. Retrieve the Eudamed Acknowledgements

Webinar 1/8 – EUDAMED Project : Understanding the Essentials Proposed Functional Architecture by Ackomas



Webinar 1/8 – EUDAMED Project : Understanding the Essentials Project Schedule





Ackomas Solution Live since 2021

- **EUDAMED UDI/DEV Experience: Simple and Accessible for Manufacturers**
 - ✓ Differences with GUDID : Multiple Countries, 6 modules
 - ✓ Confusion between Registration Schedule and Transition Periods
 - ✓ Sometimes Creation of new UDI-DI (EUDAMED rules / Packaging)
 - ✓ New identifiers: Basic UDI-DI & Master UDI-DI

- **Raising General Management's Awareness of Compliance**
 - ✓ Snowball Effect: not just in the USA and EU
 - ✓ EUDAMED : Opportunity against Unfair Competition
 - ✓ Improvement of Data quality: Production Gains and Confidence
 - ✓ Mobilization of Resources: Short-Term Deadlines



Ackomas Solution Live since 2021

- **M2M Approach: Preferable, Efficient and Cost-Effective**
 - ✓ Eudamed : Sometimes, Long Responses Times
 - ✓ Multiple XML models according to item and operation typology
 - ✓ Version Upgrades and Format Changes to consider
 - ✓ Ackomas Excel File: Simplified and Optimized Data Collection

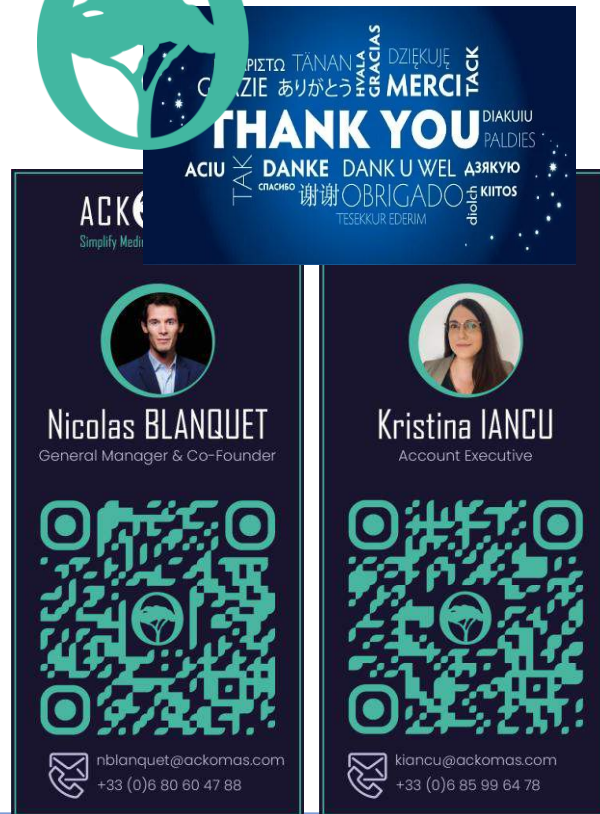
- **Launch an EUDAMED Project Now**
 - ✓ Regulatory Affairs Resources : EU Certificates
 - ✓ Involve the IT Department for the Ackomas M2M Solution
 - ✓ Cost-Effective Investment by 2025
 - ✓ Anticipate the Workload increase on EUDAMED (Q2 2025)

Next Ackomas Webinar :

2

Manually Entering Your Data into EUDAMED?

Jan 30, 25 3pm



THANK YOU

ACIU TAK DANKE DANK U WEL A3RYUO
CACHICO 谢谢 OBRIGADO dlo
TESEKKUR EDERIM

ACKOMAS
Simply Medin

Nicolas BLANQUET
General Manager & Co-Founder

Kristina IANCU
Account Executive

nblanquet@ackomas.com
+33 (0)6 80 80 47 88

kiancu@ackomas.com
+33 (0)6 85 99 64 78

- Receiving the "Eudamed Practical Guide" after the 8 Webinars
- Contact Ackomas for your general or specific questions
contact@ackomas.com / +33(0)185416167
- Contact our sales team for more information about the Ackomas solution



Valerio Gigante

Regulatory Expert | Italy & Spain Area

vgigante@ackomas.com

+33 (0)6 85 38 09 53