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DATAWEEK

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DATA FJORDS: UNLOCKING AI FOR INDUSTRY & SOCIETY

5-6 May 2026 / Oslo

SUPPORTED BY

The Research Council of Norway

data-week.eu
#DataWeek26

Bridging the legal-technical gap: practical insights on the Digital Omnibus

6 May / 11:30-13:00 CEST / Room H3

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TNO

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Tackling Compliance and its Automation

Tervel BOBEV (ART-AI)
KU Leuven – CiTiP - imec

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What IS 'Compliance'?

- Compliance as a state of affairs?
- Compliance as a property of an entity, e.g. of a law or a product?
- Compliance as (a combination of) processes?

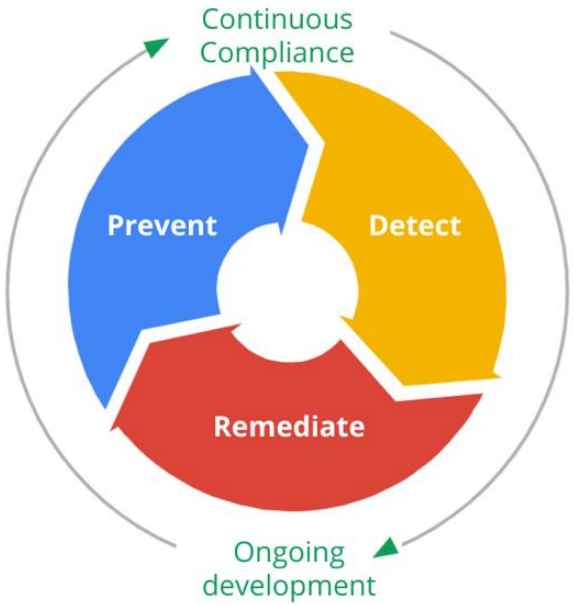
Specificity is **key** when discussing compliance and its automation.

Overview of Compliance Programs in Legal Practice

4-Stage Process: Prevent -> Detect -> Investigate -> Remediate

Design consideration for auto-compliance: which stage(s) does our solution target?

Linkage b/w 4 Stages and regulatory technology types: Regtech, Suptech, Enftech.



Source: Google

Trends in EU Digital Laws

Source: CEPS (2025), Zenner and Marcus

Research & Innovation	Industrial Policy	Connectivity	Data & Privacy	IPR	Cybersecurity	Law Enforcement	Trust & Safety	E-commerce & Consumer Protection	Competition & Single Market	Media	Finance
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	Circular Economy Act								Revision of directives on Public Procurement		

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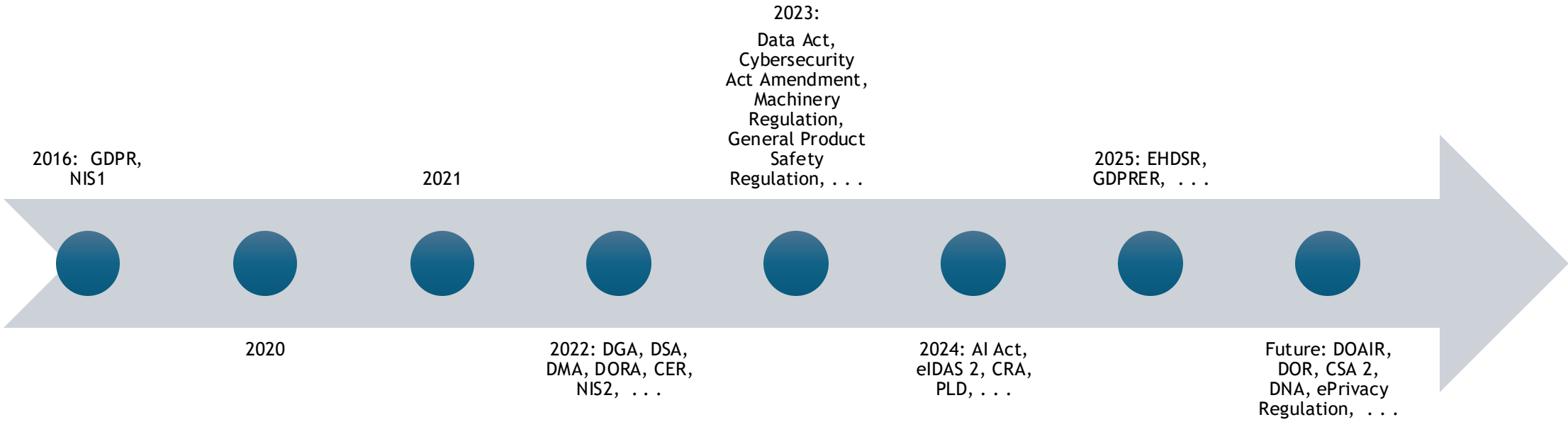
Newly Highly-Regulated in the EU Digital Decade: Dataflows and Data Markets



Trends in Compliance (EU and beyond)

Automation Rights: How to Rationally Design Humans-Out-Of-The-Loop Law

Research Paper 24-013

Orly Lobel

DORA is reshaping how Europe's financial sector thinks about compliance, and most firms still aren't ready

March 20, 2026 - 12:00 pm

Streamlining data rules

Simplifying and future-proofing

by strengthening coherence between our data rules and to ensure the broader data framework remains innovation-friendly.

One click compliance

by turning regulatory requirements into machine-verifiable tokens stored and shared through the European business wallet

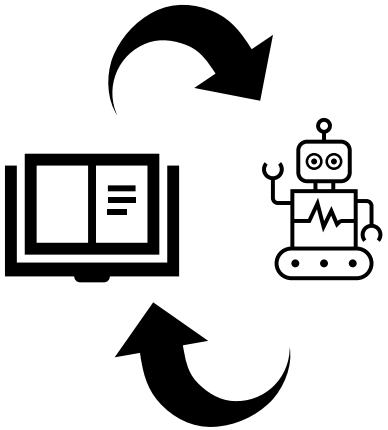
'Not fair': Ombudsman adds pressure on automated welfare compliance

New EU Compliance Ambitions

- EU Data Union Strategy: "One-Click Compliance" via "European Business Wallets"* analogously to Digital Product Passports.
  - Machine-verifiable regulatory requirements
  - Company Data -> digital compliance certificates
  - Public consultations on accountability for errors/misuse/system failures b/w company/certifier/regulator (in lieu of AILD).
- First steps in this direction: Digital Omnibus, Digital Omnibus on AI, Regulation on EBW.

Sociotechnical Challenges in Automated Compliance

- Automatically processable regulation (APR) projects elicit both legislative and technical challenges.
- APR challenges (Guitton et al. 2024): vagueness and balancing of interests; evolution of norms and statutes; lack of interdisciplinarity; agency; natural pace; workforce replacement; implementation transparency; process transparency; affordability; usability; responsibility; reality; contestability.



Core Considerations for the Omnibuses

- Do any amendments simplify (✓) or de-regulate (x) their legal subject matter?
  - Does de-regulation introduce new uncertainties for compliance?
- Are there clear and **effective** governance and enforcement mechanisms foreseen by the legislator?
- When legal obligations attach to technical processes, are there clear 'bright-line rules'? C.f. DA Art. 36 on smart contracts.

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THANK YOU!

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BRIDGING THE LEGAL-TECHNICAL GAP: PRACTICAL INSIGHTS ON THE DIGITAL OMNIBUS

ADMINISTRATIVE BURDEN REDUCTION WITH A TOOLBOX FOR COMPLIANCE AUTOMATION

May 6, 2026 - 11:30 - 13:00
MEET Ullevaal, Room H3

Kartik Chawla (TNO)
kartik.chawla@tno.nl

CIRPASS 2 Digital Product Passport

CoE DPP

CIRCLE4WIN

SM4RTENANCE

Automated Software Compliance

Kartik CHAWLA
TNO

‘A Europe fit for the Digital Age’

- Make digital transformation ‘work for people and businesses’
  - *“I sum up all of what I have set out with the term ‘tech sovereignty'. This describes the capability that Europe must have to make its own choices, based on its own values, respecting its own rules.”* Op-ed by Ursula von der Leyen on ‘Shaping Europe’s digital future’, 2020
  - *“The aim is **not more regulation**, but practical safeguards, accountability and the possibility of human intervention in case of danger or disputes.”*

EU Regulations in the Digital Sector

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	Circular Economy Act								Revision of directives on Public Procurement		

Colour coding:

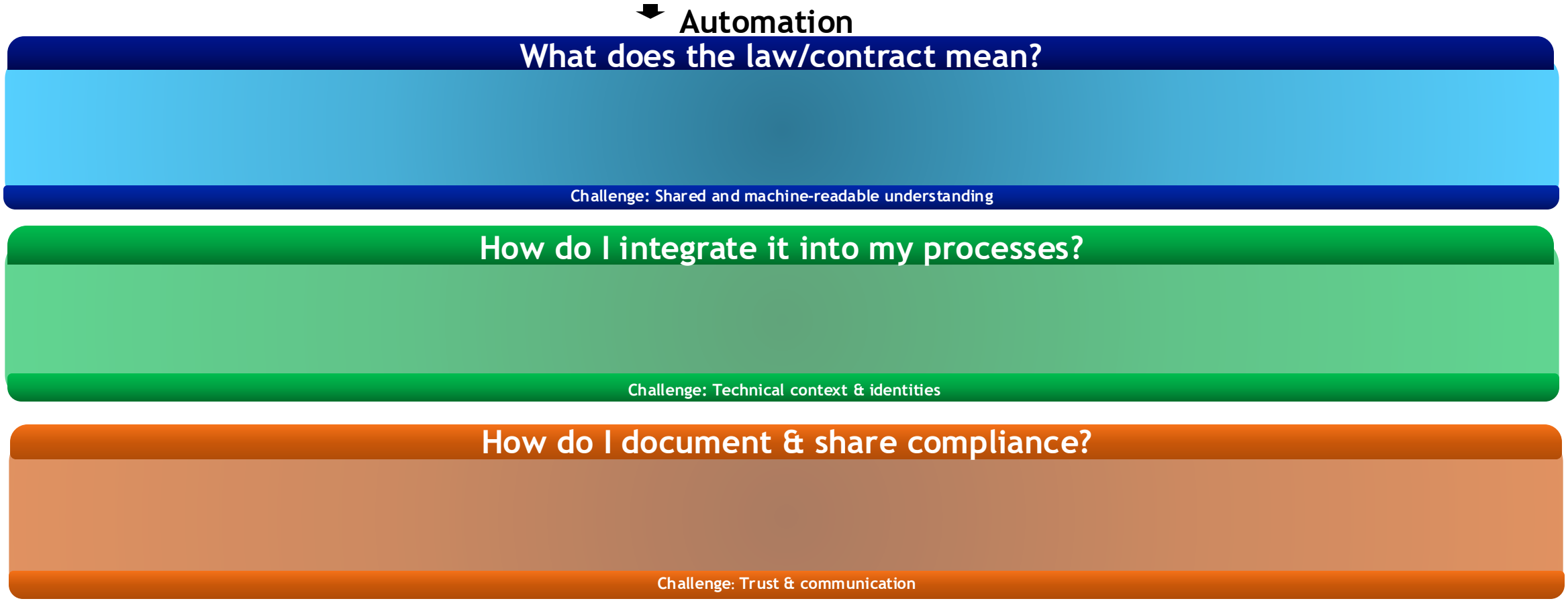
- Applicable Law — Published in the Official Journal of the EU
- In process — Proposal by the Commission entered the legislative process
- Planned initiative — Mentioned by the Commission as potential initiative

Source: A dataset of EU legal and policy instruments for the digital world – CEPS (Zenner, Markus, Zekut, 2025)

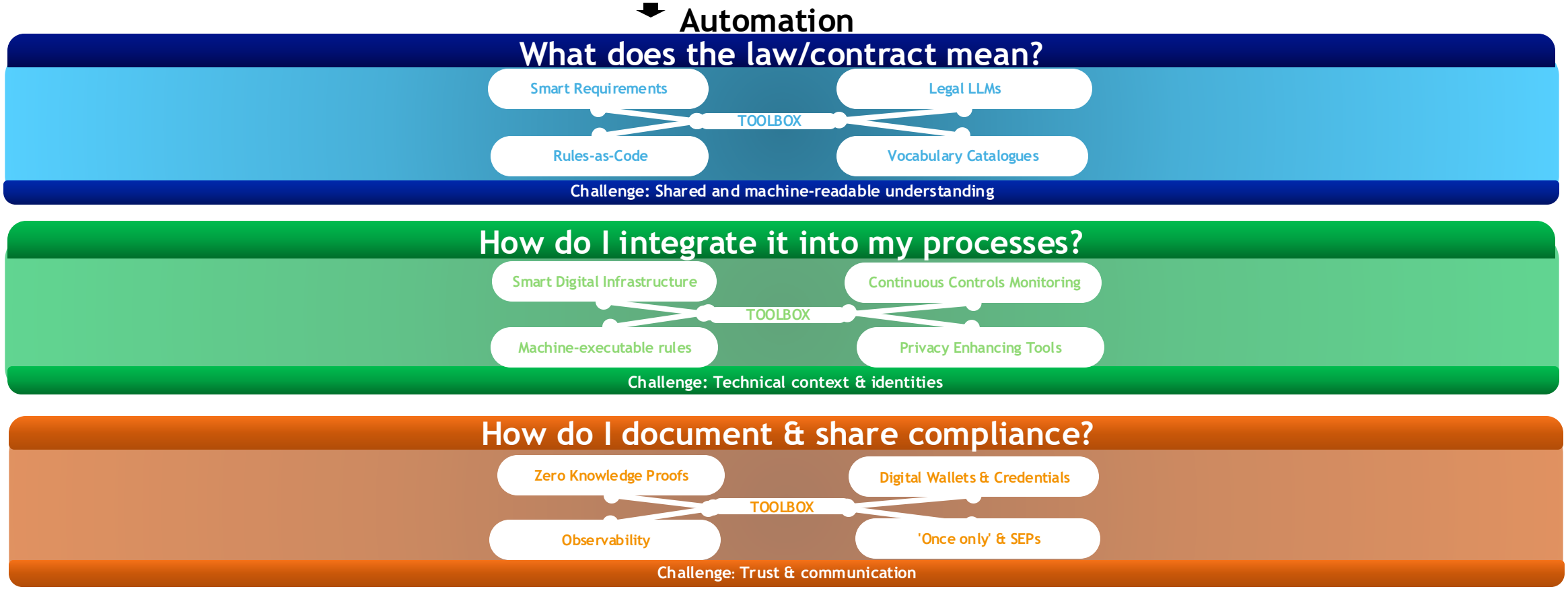
The Digital Omnibus is a part of an overall effort to ensure that compliance '*comes at a lower cost*'

- [EC] …"*a set of technical amendments … to bring immediate relief… and to stimulate the application of the digital rulebook*"
  - "The immediate objective is to ensure that compliance with the rules **comes at a lower cost**, **delivers on the same objectives**, and brings in itself **a competitive advantage** to responsible businesses."
- One-click compliance, EC Data Union Strategy
  - " *'one-click compliance' would make regulatory requirements **machine-verifiable**, turning company data into **standardised digital compliance certificates** - much like the DPP enables automatic product compliance.*"
- **How can the costs of compliance (& contracting) be reduced, for industry and for public administration?**

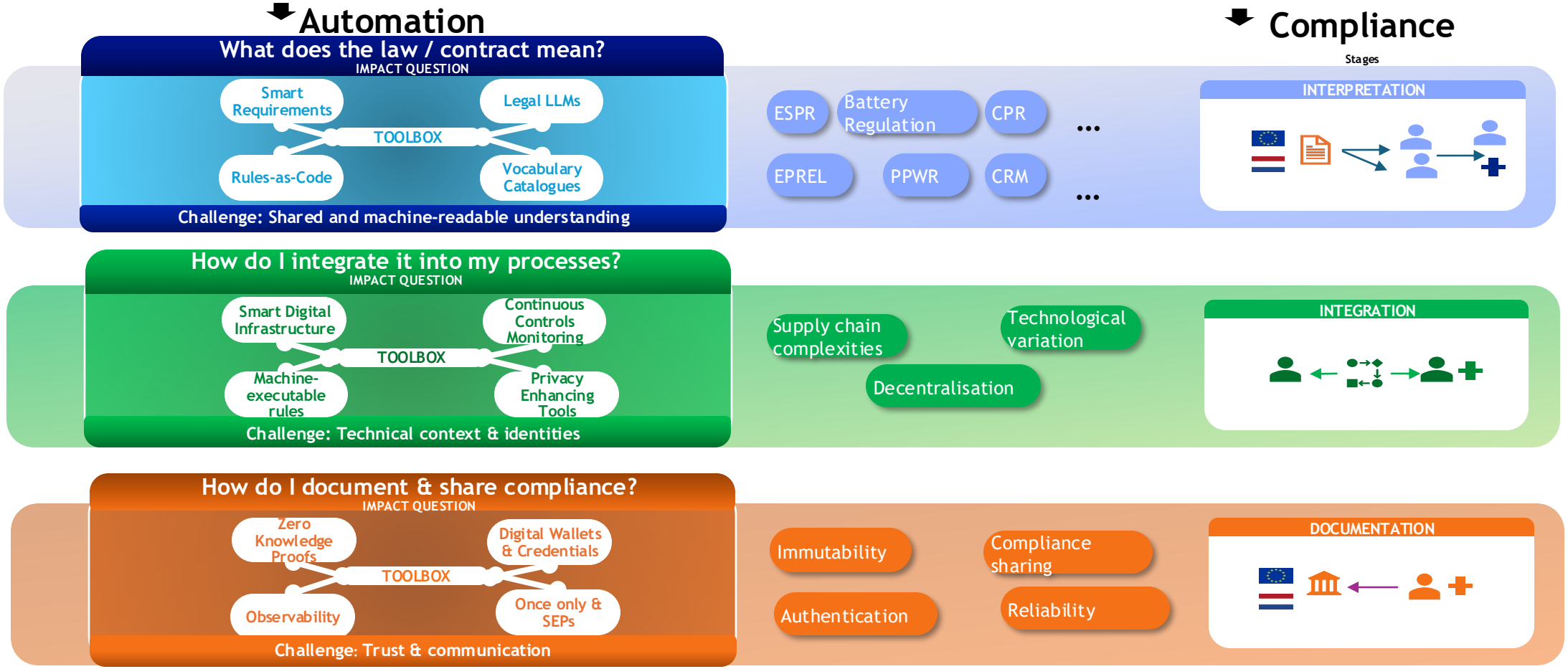
Compliance and contracting lifecycles have three stages



Each stage comes with its own challenges and solutions



This toolbox applies to Digital Product Passports

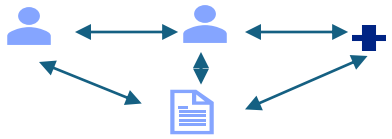


This toolbox applies to automated contracts

Contracting → **Automation**

Stages

NEGOTIATION



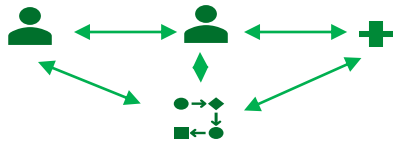
DA Art. 36(e): Consistency

What does the law / contract mean?
IMPACT QUESTION

Smart Requirements · Legal LLMs · TOOLBOX · Rules-as-Code · Vocabulary Catalogues

Challenge: Shared and machine-readable understanding

EXECUTION & MONITORING



DA Art. 36 (a, d): Access Control

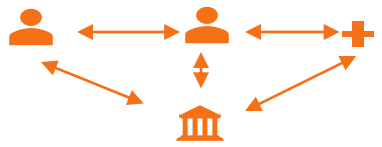
DA Art. 36 (d): Robustness

How do I integrate it into my processes?
IMPACT QUESTION

Smart Digital Infrastructure · Continuous Controls Monitoring · TOOLBOX · Machine-executable rules · Privacy Enhancing Tools

Challenge: Technical context & identities

DISPUTE RESOLUTION/TERMINATION



DA Art. 36(b): Termination & Interruption

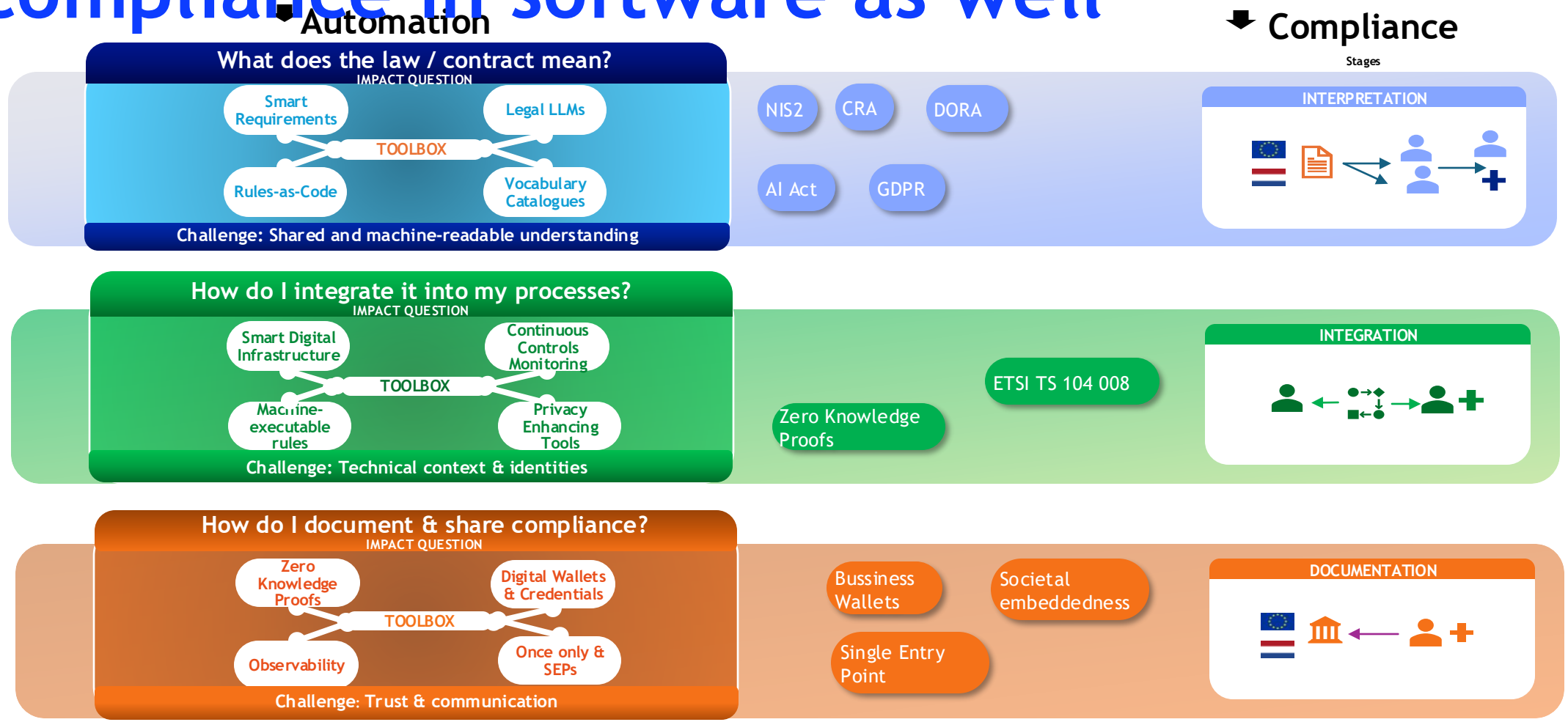
DA Art. 36(c): Auditability

How do I document & share compliance?
IMPACT QUESTION

Zero Knowledge Proofs · Digital Wallets & Credentials · TOOLBOX · Observability · Once only & SEPs

Challenge: Trust & communication

We will now apply this toolbox to compliance in software as well



Food for thought: what are your main costs of compliance?

Key takeaway 1: Simplification is important – and so is 'one-click compliance'

- "*Compliance automated where possible, human where it matters.*"
- Targeting transaction costs and behavioural biases
- For e.g.: Art. 36 is gone, but the core issues that prompted it still remain
- Regulation as a means of cost allocation

Key takeaway 2: A holistic, interoperable toolbox, across semantics, testing and documentation, is necessary to reduce administrative burdens.

- Building this toolbox in a public/private collaboration

And, a question for you:

- For your organisations and projects, what are the main costs of compliance? Would the digital omnibus change that? And/or, would this toolbox?
  - Interpreting regulatory requirements, or
  - Adapt business processes to comply, and test, or
  - Documenting and sharing compliance.

Thank you!

Feel free to reach out at

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BRIDGING THE LEGAL-TECHNICAL GAP: PRACTICAL INSIGHTS ON THE DIGITAL OMNIBUS

DATAPACT

May 6, 2026 - 11:30 - 13:00
MEET Ullevaal, Room H3

Vladimir Apraxine (KUL - CiTiP - Imec)
vladimir.apraxine@kuleuven.be

Sharon Xuereb (Camilleri Preziosi)
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DATAPACT

Funded by the European Union

This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement No 101189689.

Vladimir Apraxine
KU Leuven – CiTiP

Sharon XUEREB
Camilleri Preziosi

DataPACT: Compliance by design for data/AI operations and pipelines

Technical *tools* and *tool-supported methodologies* for compliance assessment and realization of compliance-aware data/AI pipelines and operations

7 Use cases across various domains (media and entrainment, healthcare, smart cities, customer relationship, law enforcement,…)

Six integrated tool collections with 35 tools (compliance assessment, policy and pipeline management, carbon tracker,…)

DataPACT and the Digital Omnibus

- Legal framework is the backbone of DataPACT
  - 4 EU regulations (GDPR, AIA, DA, DGA) and official guidelines are directly ingested + regulatory logic deduced through different legal artefacts
- How is the project reacting to the potential changes brought by the Digital Omnibus?
  - Neither necessary nor useful to already adapt our knowledge corpus and artefacts
- The best way to anticipate the Digital Omnibus is continuous monitoring and efficient communication with all partners
  - Identify potential new uncertainties and (technical and/or legal) obstacles

Urban Data Space: Secure, policy-based data sharing across providers and consumers

- Valuable city data (air quality, noise, traffic, infrastructure, …) is fragmented across stakeholders and systems, and legal uncertainty makes data sharing slow and case-by-case
- Data Spaces enable compliant data sharing with policy terms to be defined, negotiated, and enforced.
- Compliance needs that DataPACT seeks to address:
    - automated regulatory & policy compliance checks
    - automated policy management, enforceability, trust

Digital Omnibus' impacts on URBSPACE's obligations under the DGA and DA

- Original mandatory notification to competent national authorities transformed into voluntary regime for data intermediation services in EU public register (DGA)
  - URBSPACE would be able to use label "data intermediation services provider recognized in the Union" and the associated logo
  - Persistent uncertainties: Does that make URBSPACE more economically viable? Will there be more support from MSs and Commission?
- Vertical integration now allowed for DISs not micro and small smized enterprises, with functional separation rather than legal separation (DGA)
  - Relevant as URBSPACE is by a university

Digital Omnibus' impacts on URBSPACE's obligations under the DGA and DA

- Restriction of business-to-government obligations to share business data generated by connected products and related services (DA)
  - exceptional need in response to public emergency or tasks in public interest (official statistics, mitigation or recovery from public emergency) vs exceptional need which necessitates the use of data in the public interest, necessary for responding to, mitigating, or supporting the recovery from a public emergency
  - Persistent uncertainties: link between exceptional need and public emergency? National approaches to public emergency? Stages of public emergency?
  - New uncertainty: public interest previously only for mitigation and recovery → public interest and public emergency now as cumulative, including for response: additional layer of complexity -> mitigation and recovery has implied assumption of public interest, but what about response?

MUSES: Emotion Recognition with AI Solutions for Movies

- **MUSES** reveals real emotional reactions using EEG signals → authentic, direct-from-brain insights to determine viewer engagement
- How it works?
  1. Models were trained using pre-consented, publicly available EEG datasets
  2. EEG signals were recorded during video stream sessions
  3. Emotion inference determined from recorded viewing data
  4. Visual dashboard shows where viewers are thrilled, bored, or disengaged

- Compliance needs that DataPACT seeks to address:
  - Transparency: Pipelines must be understandable & traceable for operators and auditors
  - Sensitive data: EEG = biometric data → explicit consent required; high-risk AI system
  - Fairness: Model training & inference must be unbiased across demographics

How the Digital Omnibus proposals may impact MUSES (GDPR)

- Pre-Digital Omnibus Definition of Personal Data

vs

Revision of the definition of personal data in the context of Emotional Recognition

- Listed legal bases of processing under Article 6 GDPR

vs

New! Processing personal data for the development and operation of an AI system will constitute an Article 6(1) legitimate interest

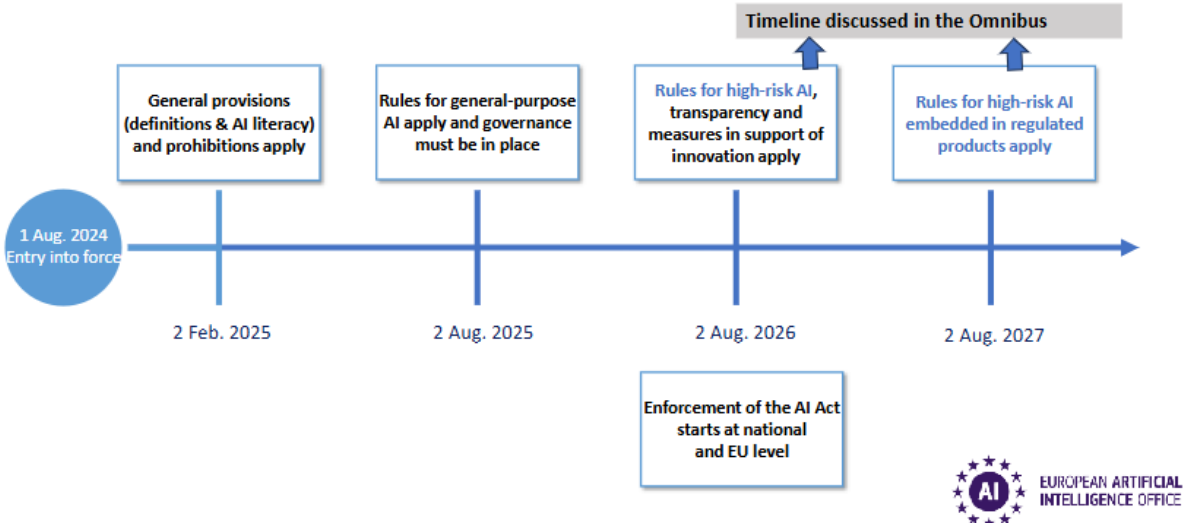
- New! A definition of scientific research to include commercial interest and further processing for scientific research purposes is confirmed as compatible with the original purpose

CarePath: AI-based healthcare support system

- CarePath bridges the high-risk management gap during a patient's transition from hospital to home
- How it works?
  1. Inadequate monitoring leads to higher readmission rates and adverse events because clinicians lack continuous data for discharge decision
  2. AI-Driven Support System to identify patients at high risk of complications and recommends optimal discharge timing
  3. Non-intrusive monitoring of patient status via IoT activity trackers, smart scales, BP monitors, and sleep analysis
  4. Data flows from hospital-based hubs to central databases for AI processing
- Compliance needs that DataPACT seeks to address:
  - Fairness: training datasets must be unbiased to prevent discrimination e.g. based on characteristics like age or gender
  - Consent and Sensitive Personal Data: processing of sensitive patient health information with requirements for patient permission through consent and consent management
  - Integrated Compliance Pipelines: ensuring that compliance against legal and ethical constraints and monitoring algorithms to remain aligned with healthcare guidelines

How the Digital Omnibus proposals may impact **CarePath** (AIA)

- Timeline extension: dependent on Industry Standards of High-Risk Systems



- Alignment with GDPR: Special categories of personal data may be processed to ensure data bias detection and correction, subject to appropriate safeguards

- Simplified modalities for SMEs and Small Mid Caps (new)

Digital Omnibus Proposal Mapping to UC Scenarios: A consideration

	MUSES	CAREPATH	URBSPACE
Revision of the definition of personal data	X	X	X
Processing personal data for the development and operation of an AI system will constitute an Article 6(1) legitimate interest (Article 88c)	X	X	X
New definition of scientific research	X	X	X
Extended compliance timelines for high-risk AI systems	X	X	
Removal of mandatory AI literacy requirement for providers and deployers	X	X	X
Special categories of personal data may be processed to ensure data bias detection and correction (Article 4a AIA)	X	X	X
Obligations for providers to register is removed if they conclude that these systems are not high-risk due to their narrow or procedural tasks	X	X	
Scope of testing high-risk AI systems in AI regulatory sandboxes is expanded	X	X	
Voluntary regime for DISs (DGA)			X
Vertical integration (DGA)			X
Restriction of business-to-government obligations to share business data generated by connected products and related services (DA)	X	X	X
Stronger refusal powers of data holders	X	X	X

Conclusion

- Unprecedented reform to EU laws
- Current status: Uncertainty prevails!
- No significant impact on project uptake; updates to knowledge corpus and raising participants' awareness
- Remaining concerns
- Key takeaway: wait and see; continuous monitoring by the DataPact legal team

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THANK YOU!

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ACHILLES

BRIDGING THE LEGAL-TECHNICAL GAP: PRACTICAL INSIGHTS ON THE DIGITAL OMNIBUS

ACHILLES

May 6, 2026 - 11:30 - 13:00
MEET Ullevaal, Room H3

Julie Mannekens (KUL - CiTiP - Imec)
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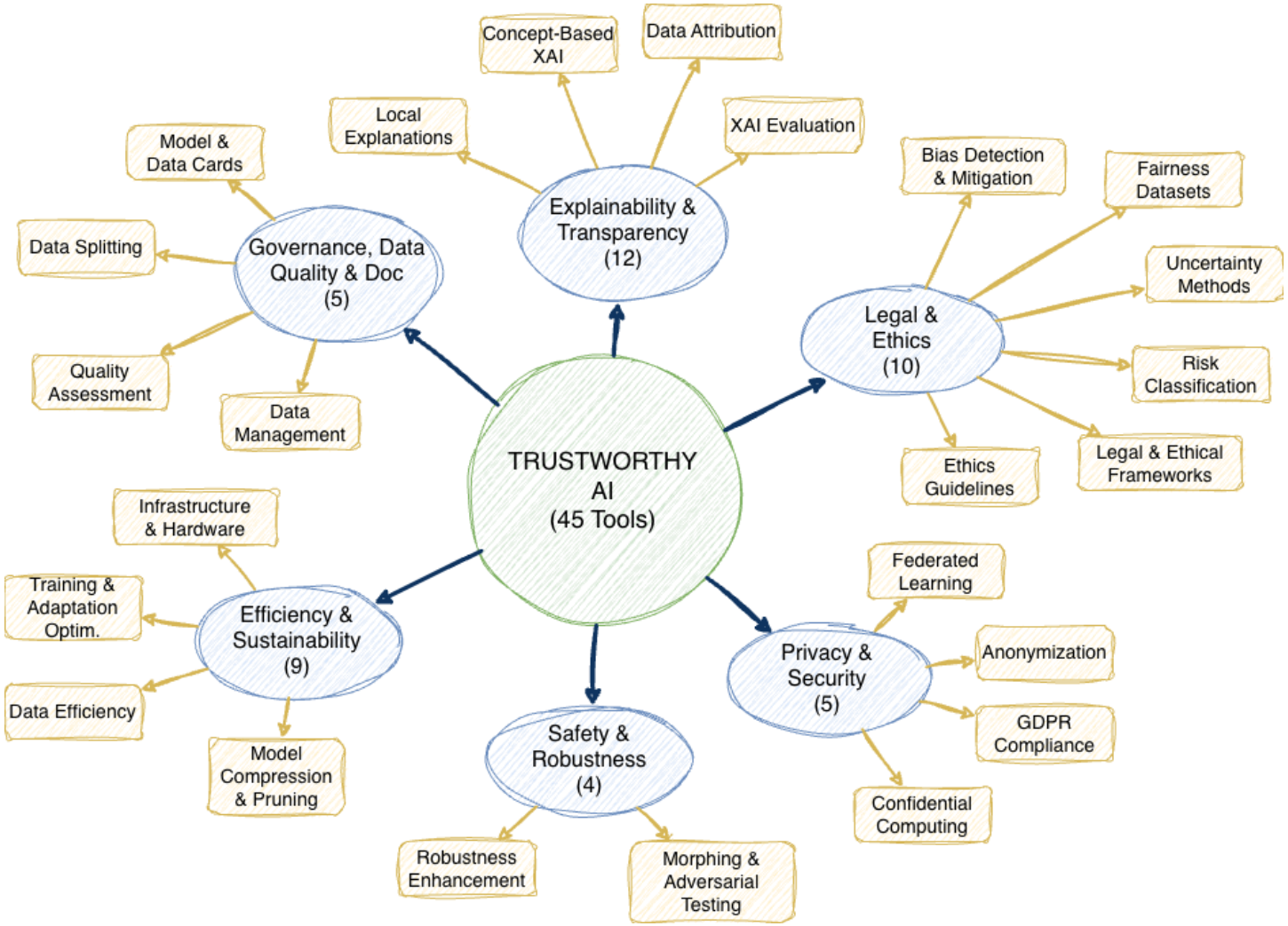
Julie MANNEKENS
KU Leuven – CiTiP

ACHILLES project

- Development of **ACHILLES ASSETS** that support developing trustworthy, secure, and efficient data ecosystems
  - Integration within the IDE
- Validation trhough **USE CASES:**
  - SCRIPTA (AI-generated script validation)
  - Healthcare (ML-based screening and diagnostic tools)
  - HERA (compliance within the pharmaceutical sector)
  - ID verification (deep learning models used in identity document verification)

ACHILLES project - overview ASSETS



ACHILLES – Impact Digital Omnibus

DO amendment	ACHILLES ASSETS	Healthcare UC	ID verification UC	HERA UC	SCRIPTA UC
Definition of personal data	x	x	x	x	x
Further processing for research	x	x	x	x	x
Legitimate interest for development and operation of AI	x	x	x	x	x
Residual processing of sensitive data for development and operation of AI	x				x
Processing of biometric data for verification			x		
AI Literacy	x	x	x	x	x
Permission to process sensitive data to de-bias AI systems	x	x	x		

Impact Digital Omnibus – Definition of personal data

- Art. 4(1) GDPR: ‘information relating to an identified or identifiable natural person’
  - Identifiability: Does an entity has the means reasonably likely to be used to identify a natural person
- Relative approach: personal data in the hands of one person not necessarily personal data in the hands of another person

- Tool for detection of personal data
- Opportunities in data sharing? ! **However,**
  - Technical underlying assessment is not straightforward
  - Recipient should act as a seperate controller

Impact Digital Omnibus – Residual processing of sensitive data

- Prohibition to process sensitive data, unless one of the exceptions in Article 9.2 GDPR applies
- Art. 9.2(k) GDPR: new exception for the residual processing of sensitive data for the development and operation of AI systems/models
  - Appropriate measures to avoid collection and processing of sensitive data
  - Any sensitive data that is nevertheless processed, must be removed
  - If disproportionate effort to remove such data, data cannot be used to generate outputs or be disclosed

- Pragmatic approach focusing on strong privacy-by-design measures
  - ! **However**, technical partners noted that such mitigation measures are already being applied in practice, but implementation remains challenging.

Impact Digital Omnibus – Biometric verification

- Prohibition to process sensitive data, unless one of the exceptions in Article 9.2 GDPR applies
- Art. 9.2 (l) GDPR: new exception for processing of biometric data for biometric verification (1:1 comparison)
  - >< biometric identification (1:n comparison)
- Under the sole control of that data subject
  - Stored at the side of the data subject
  - Stored in encrypted form at the side of the controller and the encryption is key is held by the data subject

- Technical partners noted that they are already designing their systems this way in practice
--> Explicit consent would no longer be necessary

Thank you!

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CERTAIN

BRIDGING THE LEGAL-TECHNICAL GAP: PRACTICAL INSIGHTS ON THE DIGITAL OMNIBUS

CERTAIN

May 6, 2026 - 11:30 - 13:00
MEET Ullevaal, Room H3

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CERTAIN

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Olena DENYSENKO
University of Tartu

CERTAIN project

Certification for Ethical and Regulatory Transparency in AI

VISION

A cohesive, compliant ecosystem for AI stakeholders — fostering trust, transparency and innovation in the European data economy.

FOCUS AREAS:

- AI Certification
- Regulatory Compliance
- Data Governance
- Sustainable AI

KEY OBJECTIVES

Traceability Enable traceability of critical AI system information

Guidelines Legally & ethically compliant AI assessment

Compliance Tools Tools for data space providers & data holders

Assessment Methods to assess AI compliance with EU regulations

Certification Certification procedures for AI systems

Evidence Empirical evidence of the project's framework

Community Certification procedures for AI systems

7 OPERATIONAL PILOTS

- **P1 Biometrics** Developing AI-driven biometric recognition for high-risk border management & airline boarding
- **P2 Health** AI support to enhance early detection and monitoring of psychiatric risks in youth
- **P3 Energy** AI systems for RECs to manage demand forecasting & consumption optimization
- **P4 Human Resources** Enabling the trusted & secure publishing of sensitive HR data
- **P5 Data Holders** Supporting SMEs in navigating legal complexities when entering AI data markets
- **P6 Finance** Generating personalized investment recommendations aligned with customers' risk profile
- **P7 IT/MLOps** Regulatory compliance automation

WP3: Legal, Ethical & Social Compliance Guidelines

D3.1	D3.2	D3.3	D3.4 ★	D3.5
Legal Requirements	Ethical Requirements	Social Requirements	Guidelines for entering AI data markets	Multidisciplinary Guidelines for AI stakeholders

★ *Under active development - presented today*

What D3.4 delivers:

198 Requirements Extracted	Unified Requirements	Logical Decision Tree Model (LTM)	Interactive Compliance Tool
Data Act, DGA, GDPR, AI Act Art.10 systematically mapped	Across 10 thematic clusters with cross-instrument overlap analysis	Yes/no questions → tailored into 2-tier compliance output	Live prototype feeding into D3.5 final tool

THE LOGICAL DECISION TREE MODEL – HOW IT WORKS

Section 1	Section 2	Section 3	Section 4
WHO ARE YOU?	**WHAT DATA DO YOU HAVE?**	**WHAT DO YOU WANT TO DO?**	**ADDITIONAL CONTEXT**
Role – Size - Establishment	Personal · Special category Trade secrets · IoT	Data space · B2B sharing AI supply · Intermediary	3rd country / High-risk AI / Research purpose

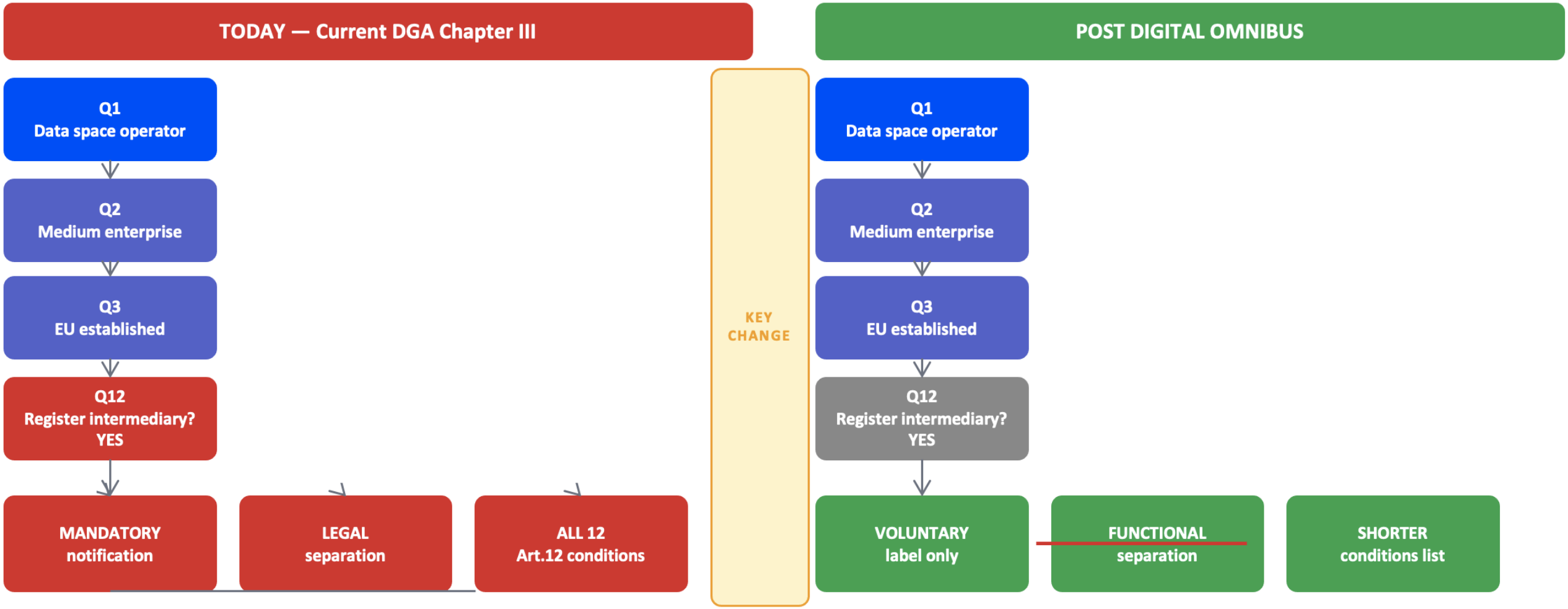
OUTPUT — Tailored compliance requirements

TIER 1 **MUST comply**
Minimum legal obligations

TIER 2 **BEST practice**
Ethical & social excellence

Persona 1 - Data Intermediary Service Provider

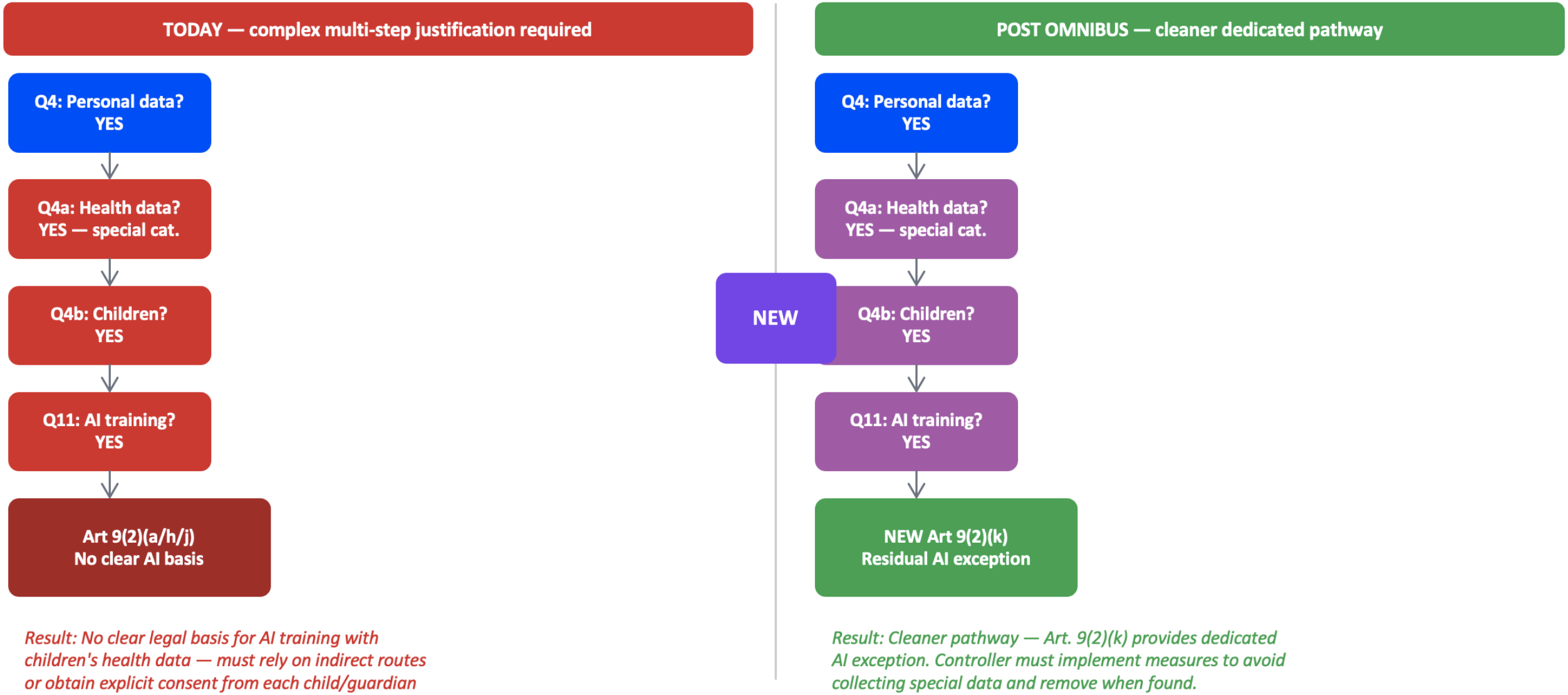
Role	Data intermediary service provider — facilitates data sharing between IoT data holders and AI developers
Data	Non-personal industrial IoT data + some personal operational data
Location	EU-Established
Goal	Operate a certified EU data space for connected manufacturing devices

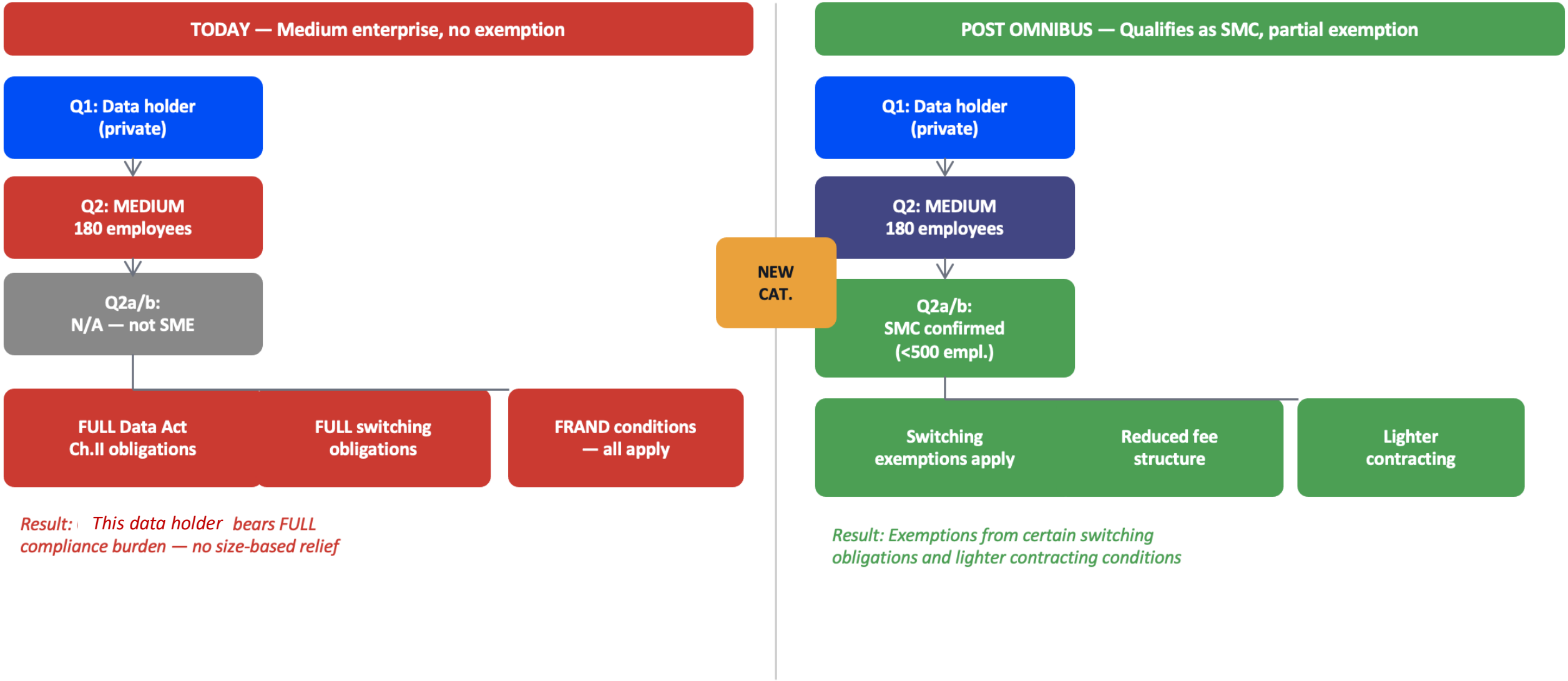


Key change: Mandatory → Voluntary. Legal separation → Functional separation. Conditions list significantly shortened.

Persona 2 - Data Holder (Child Psychiatry)

Role	Data holder — health tech company providing digital diagnostic support tools for childhood psychiatric disorders
Size	Medium SME — 180 employees, €22M turnover. NOT micro/small — no Chapter II exemption. MAY qualify as SMC (under 500) post-Omnibus
Data	Children's health data (psychiatric), biometric monitoring data, genetic markers — ALL GDPR Art. 9 special categories
Location	EU-Established
Goal	Supply anonymised training datasets to AI developers for diagnostic model development


TODAY — complex multi-step justification required
Q4: Personal data?
YES
Q4a: Health data?
YES — special cat.
Q4b: Children?
YES
Q11: AI training?
YES
Art 9(2)(a/h/j)
No clear AI basis
Result: No clear legal basis for AI training with children's health data — must rely on indirect routes or obtain explicit consent from each child/guardian
POST OMNIBUS — cleaner dedicated pathway
Q4: Personal data?
YES
Q4a: Health data?
YES — special cat.
NEW
Q4b: Children?
YES
Q11: AI training?
YES
NEW Art 9(2)(k)
Residual AI exception
Result: Cleaner pathway — Art. 9(2)(k) provides dedicated AI exception. Controller must implement measures to avoid collecting special data and remove when found.


TODAY — Medium enterprise, no exemption
Q1: Data holder (private)
Q2: MEDIUM 180 employees
Q2a/b: N/A — not SME
FULL Data Act Ch.II obligations
FULL switching obligations
FRAND conditions — all apply
Result: This data holder bears FULL compliance burden — no size-based relief
NEW CAT.
POST OMNIBUS — Qualifies as SMC, partial exemption
Q1: Data holder (private)
Q2: MEDIUM 180 employees
Q2a/b: SMC confirmed (<500 empl.)
Switching exemptions apply
Reduced fee structure
Lighter contracting
Result: Exemptions from certain switching obligations and lighter contracting conditions

THREE TAKEAWAYS

01

The Digital Omnibus impact is NOT uniform

For data intermediaries: structural deregulation — mandatory regime becomes voluntary, legal separation becomes functional. For data holders supplying AI training data: not simpler, but clearer — new pathways that reduce legal uncertainty.

02

Size matters — and it will matter differently

The new SMC category (< 500 employees) extends exemptions and lighter regimes to a much larger group of actors. Organisations that currently bear full compliance burdens may find significant relief — but only if the Omnibus is adopted as proposed.

03

Guidelines need to be living documents

D3.4 is built on current law. The Digital Omnibus is not yet law. The LTM architecture is deliberately designed to be updatable — new questions, new exemptions, new pathways can be added without rebuilding from scratch.

Thank you!

Feel free to reach out at

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CERTAIN Stakeholder Registration

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Thank you!

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