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EU Digital Omnibus: Pharma & Medical Device AI Compliance

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Executive Summary

The **EU Digital Omnibus** package – unveiled in late 2025 – is a coordinated legislative initiative to *simplify and streamline* the EU's digital rulebook. It comprises two intertwined proposals: a **Digital Omnibus on AI** (amending the EU **AI Act** of 2024) and a broader **Digital Omnibus Regulation** (amending assorted data, cybersecurity and electronic communications laws, including the GDPR, Data Act, ePrivacy Directive, NIS2, etc.) (datamatters.sidley.com) (www.europarl.europa.eu). These targeted amendments are explicitly designed to *reduce the regulatory burden* on businesses while preserving high standards of safety, data protection and consumer trust (digital-strategy.ec.europa.eu) (www.edpb.europa.eu).

For the life sciences sector (pharmaceuticals, biotech and medical devices), **key changes** include:

- **Extended Compliance Timelines for AI:** The amended Article 113(c) sets fixed application dates for Chapter III, Sections 1–3, except Article 6(5): **2 December 2027** for systems classified as high-risk under Article 6(2)/Annex III and **2 August 2028** for systems classified as high-risk under Article 6(1)/Annex I, including qualifying AI in medical devices. Plan against those dates; the enacted provision does not make them contingent on a Commission decision about standards. Other AI Act provisions have separate application dates.

- **Integrated Conformity Assessment:** The AI Omnibus explicitly confirms that for high-risk AI systems that are **also regulated products** (e.g. " AI as a Medical Device"), the **EU AI Act's requirements will be fulfilled through the existing MDR/IVDR conformity assessment** regime. In other words, manufacturers can use a *single certification/QMS process* to address both device and AI obligations (datamatters.sidley.com) (www.arnoldporter.com). Likewise, the procedure for designating notified bodies is streamlined: a single application/assessment will suffice for both MDR/IVDR and AI Act approval. This avoids duplication of testing and accelerates the availability of AI-competent notified bodies (www.osborneclarke.com) (www.arnoldporter.com).
- **Real-World Testing and Sandboxes:** The AI Omnibus expands the EU's regulatory sandboxes and **pre-market testing regime**. High-risk AI devices (Annex I) can now be tested in 'real-world conditions' *before* formal market placement (www.osborneclarke.com) (www.arnoldporter.com) – a boon for companies piloting clinical AI systems. The Commission will also establish an EU-level AI sandbox and require cross-border collaboration among national sandboxes, allowing pharma and medtech firms to refine AI products under regulatory supervision (www.osborneclarke.com) (www.arnoldporter.com).
- **Research & Bias Detox:** Pharmaceutical and biotech firms benefit from clearer research exemptions. EU guidance (as pledged in the Omnibus **Staff Working Document**) will clarify that pre-clinical research and performance studies do **not** trigger full AI Act obligations (www.osborneclarke.com) (datamatters.sidley.com). For bias detection and correction, original Article 10(5) already contained a narrowly conditioned special-category-data permission for high-risk providers (Recital 70). Article 4a carries it forward; paragraph 2 extends permission to deployers of high-risk systems and providers/deployers of other systems and models, subject to strict necessity and the paragraph 1 safeguards.
- **Administrative Relief:** Article 4 retains an obligation for providers and deployers to support staff AI literacy; it does not require guaranteeing any individual's literacy level. Article 49(2) still requires providers, or their authorised representatives where applicable, to register themselves and systems they conclude are not high-risk under Article 6(3) before market placement or putting into service. SME-friendly measures (simpler documentation, penalty discounting) are **extended to "small mid-cap" companies**, recognizing that life sciences scale-ups often exceed the SME threshold (www.osborneclarke.com) (www.europarl.europa.eu). Similarly, data protection burdens are eased: e.g. higher notification thresholds for breach notifications, unified DPIA lists, and exemptions from some transparency notices are proposed (www.arnoldporter.com) (www.edpb.europa.eu).
- **Data Governance Adjustments:** The broader data Omnibus remains a proposal. For health-data research, an Article 6 legal ground and an applicable Article 9 derogation are both required; legitimate interests alone are insufficient. The proposed residual special-category-data exception is narrowly framed and should not be treated as permission for routine intentional collection of patient data for AI training. The Council's 21 October 2026 mandate maintains the current personal-data definition, so a broad new pseudonymisation exemption should not be assumed.

In sum, the **Digital Omnibus** package seeks to reconcile Europe's high standards with the urgent need for agility. If enacted, it would save EU businesses an estimated **€5 billion** in compliance costs by 2029 (digital-strategy.ec.europa.eu) (eur-lex.europa.eu). For pharma and medtech companies, the package offers longer

lead-times, clearer rules and reduced paperwork on AI and data, which is likely to accelerate innovation – *provided* companies also maintain robust safety and data safeguards. Regulatory authorities (Commission, EDPB/EDPS) have signalled support for simplification in principle, but continue to underscore that no cornerstones (e.g. personal data protections) should be weakened (www.edpb.europa.eu) (www.europarl.europa.eu). In practice, life sciences stakeholders must monitor the Omnibus' progress and prepare to adapt their compliance strategies accordingly.

Introduction

The EU's **digital regulatory framework** has grown extensive and complex. Over the past decade, Europe has enacted pioneering laws in data protection (the GDPR), cybersecurity (NIS-Directive/NIS2), artificial intelligence (the 2024 AI Act), medical devices (MDR/IVDR), digital products (Cybersecurity Act, Data Act, etc.), and more. While these rules aim to ensure safety, privacy and trust, stakeholders have increasingly argued that *cumulative burdens* now hamper competitiveness. In calls dating from 2024-2025, EU leaders and industry reports warned that regulatory complexity risked slowing innovation across sectors, including life sciences (eur-lex.europa.eu) (www.europarl.europa.eu).

Against this backdrop, the Commission launched a **Digital Simplification agenda** under the mantra "A simpler and faster Europe" (eur-lex.europa.eu). The centerpiece is the **Digital Omnibus** – a set of narrow, technical amendments intended to give immediate relief. Announced on 19 November 2025, the package has two pillars (datamatters.sidley.com): (1) **Digital Omnibus on AI** (amend the EU AI Act and related legislation) and (2) **Digital Omnibus Regulation** (amend a sweep of existing digital laws, e.g. GDPR, Data Act, ePrivacy, NIS2). Together these proposals aim to lower compliance costs while "promoting Europe's highest standards" of rights and safety (digital-strategy.ec.europa.eu).

For **pharmaceutical and medical device companies**, the timing is salient. Many in the **life sciences industry** are embracing AI: from biotech firms applying machine learning to drug discovery, to medtech companies embedding AI in diagnostics and implants. An October 2024 Medical Technology feature, citing GlobalData's companies database, reported around **7,754 European healthcare companies with exposure to AI**. That estimate describes exposure, rather than verified adoption or a count of health-AI startups. These firms interact with both digital and sectoral law – for example, an AI-driven diagnostic tool must satisfy the new AI Act *and* the Medical Devices Regulation (MDR). Likewise, pharma firms using AI for clinical trial analysis must comply with GDPR for patient data.

Thus the **Digital Omnibus** affects life sciences on two fronts: the **horizontal AI/data/cyber laws** and the **sectoral specific rules** (MDR/IVDR/Medicinal Products Regulation, etc.). In particular:

- The **AI Act** (Regulation 2024/1689) classifies device or IVD AI as high-risk under Article 6(1) only where both conditions are met: the AI is itself a product, or is intended as a safety component of a product, covered by Annex I legislation; and that product must undergo third-party conformity assessment. The June 2025 AIB/MDCG guidance documented the original **2 August 2027** timetable for Annex I high-risk systems. Amended Article 113(c)(ii) now sets **2 August 2028** for Chapter III, Sections 1–3, except Article 6(5), for those systems. Other AI Act provisions have separate application dates.

- **GDPR and Data Rules:** Pharma and medtech handle vast volumes of personal (often health) data – in R&D, trials, pharmacovigilance, patient apps, etc. Proposed GDPR clarifications on pseudonymization, research use, and breach reporting key to life sciences are part of the Digital Omnibus Regulation.
- **Cyber & ePrivacy:** Medical institutions and device manufacturers are also subject to new cybersecurity (NIS2) and privacy (ePrivacy) rules. The omnibus proposes modest tweaks here (e.g. simplifying incident-reporting channels and templates (Council mandate; Commission proposal summary), easing cookie consent burdens) that can have downstream impact on health tech compliance.

In this report, we **systematically dissect** the Digital Omnibus provisions and their implications for pharmaceutical and medical device compliance. We combine legislative analysis, industry commentary and academic insights to detail *what is changing and why it matters*. We begin with the AI-related amendments, then turn to data protection and other horizontal laws, and finally illustrate with examples. We draw on official sources (Commission communications, regulatory opinions), law firm analyses, and independent studies to ensure each claim is evidence-backed (digital-strategy.ec.europa.eu) (datamatters.sidley.com) (www.arnoldporter.com) (www.edpb.europa.eu). Our intent is to provide life sciences stakeholders – from regulators to CEOs – with an authoritative, granular resource on the Digital Omnibus.

The EU Digital Omnibus Package: Scope and Context

In November 2025 the European Commission unveiled a **broader digital package** with multiple components (digital-strategy.ec.europa.eu) (www.europarl.europa.eu). Central to this was the **Digital Omnibus**: an urgent "set of technical amendments to a large corpus of digital legislation" designed to *streamline rules on AI, cybersecurity and data* (digital-strategy.ec.europa.eu) (www.arnoldporter.com). The stated goal is 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" (digital-strategy.ec.europa.eu). The Commission estimated these changes could save EU businesses at least **€5 billion** by 2029 (digital-strategy.ec.europa.eu) (eur-lex.europa.eu). (Separate elements – not the focus here – include a *Data Union Strategy* and a proposed *European Business Wallet* for digital identities (digital-strategy.ec.europa.eu).)

The Omnibus comprises **two legislative proposals** issued 19 Nov 2025:

1. **Digital Omnibus on AI Regulation** (AI Act amendments): A Regulation amending the newly adopted EU AI Act (Reg.2024/1689) to ease implementation challenges. It also amends various related frameworks (notably it adds a small amendment to the EU Civil Aviation safety rules (Reg 2018/1139) to align on AI, as well as extending obligations in the Cybersecurity Act's AI building blocks). This is sometimes called the "AI Omnibus".
2. **Digital Omnibus Regulation Proposal**: A Regulation amending a broad array of acts in the "digital acquis": data laws (GDPR 2016/679, Data Act 2023/2854, Free Flow of Non-Personal Data Reg 2018/1807, Data Governance Act 2022/868, Open Data Directive 2019/1024), privacy and electronic

communications (ePrivacy Directive 2002/58), cybersecurity (NIS2 Dir 2022/2555), platform regulation (repealing Reg 2019/1150), and more (eur-lex.europa.eu). In effect, it "integrates" DGA/ODD into the Data Act and sweeps away duplicative or outdated requirements.

These proposals followed extensive stakeholder input. Throughout 2025 the Commission held consultations and a public Call for Evidence on digital simplification, receiving input from industries (incl. MedTech Europe, pharma groups like EFPIA), academia and national authorities. Common feedback was that overlapping rules and deferred standards threatened market readiness. The Commission's Staff Working Document recognizes this: "implementation and harmonised standards for high-risk AI have fallen behind schedule… driving compliance burdens above the level originally envisaged" (www.osborneclarke.com). Similarly, the cost of navigating GDPR uncertainties (e.g. for pseudonymized clinical data) was flagged. The Omnibus thus is explicitly a "first step" toward an "agile EU digital rulebook" (digital-strategy.ec.europa.eu) (eur-lex.europa.eu).

As of **24 October 2026**, the two files have different legal statuses. The AI Omnibus entered into force on 27 July 2026. The broader data Omnibus remains pending: the Council agreed its negotiating position on 21 October 2026 and will begin negotiations once Parliament adopts its position. Companies should distinguish enacted AI Act amendments from proposed GDPR, ePrivacy and cybersecurity changes.

Table 1 (below) summarizes the **key AI-specific amendments** proposed (further details follow). A broader summary of the data/cyber amendments is then provided.

System/Obligation	Current (AI Act)	Proposed (Digital Omnibus)	Implication
High-risk AI obligations (Chapter III, Sections 1–3, except Article 6(5))	Original schedule: Annex III in August 2026; Article 6(1)/Annex I in August 2027	Enacted Article 113(c): **2 December 2027** for Article 6(2)/Annex III and **2 August 2028** for Article 6(1)/Annex I	Fixed application dates for these provisions; other AI Act duties follow their own schedule.
Legacy high-risk AI systems (Article 111(2))	Transition limited to high-risk systems outside Article 111(1), placed on the market or put into service before the relevant Chapter III application date under Article 113	Under Article 111(2), the Regulation applies to operators of those systems only if significant design changes occur from that date; Article 5 prohibitions remain applicable	In any case, providers and deployers of high-risk systems intended for use by public authorities must take the necessary steps to comply by **2 August 2030**.
Conformity assessment (AI+sector laws)	Separate AI assessment (in theory) and device (MDR/IVDR)	**Integrated** assessment: MDR/IVDR conformity procedure covers AI requirements (datamatters.sidley.com) (www.arnoldporter.com)	Single combined QMS and audit covers both; reduces duplication and speeds compliance.
Notified body designation	Separate applications for AI Act vs MDR/IVDR	One unified application/assessment possible for both frameworks (www.osborneclarke.com) (www.arnoldporter.com)	More notified bodies can qualify for AI-device testing; blunts the NB shortage.
AI literacy measures (Article 4)	Original duty concerned sufficient staff AI literacy	Amended Article 4 requires measures supporting staff AI literacy, without guaranteeing an individual level	The obligation remains; national authorities supervise and enforce it.

System/Obligation	Current (AI Act)	Proposed (Digital Omnibus)	Implication
Registration of Annex III systems exempted under Article 6(3)	Providers must assess the applicable classification and registration provisions	Article 49(2) retains registration of the provider and the exempted system before placement on the market or putting into service	This is a specific Annex III duty, not a general registration requirement for ordinary low-risk administrative tools; Article 60 concerns testing.
AI bias detection (special-category data)	Original Article 10(5) already permitted strictly necessary bias processing by high-risk providers, subject to safeguards (Recital 70)	Article 4a carries this forward and extends permission under paragraph 2 to additional providers/deployers and systems/models	The extension remains subject to strict necessity and paragraph 1 safeguards; it is not a general patient-data retraining permission.

Table 1: Key proposed amendments to the AI Act (via the Digital Omnibus on AI) and their relevance to life sciences. "MDR/IVDR" = Medical Device/IVD Regulations.

AI Act Amendments: MedTech and Pharma Implications

The **AI Omnibus** proposal [COM(2025)836 final] primarily tweaks the EU AI Act 2024. The principal objective was to ease implementation of the Act's **Chapter III requirements** for high-risk AI, which were scheduled to accelerate from August 2026 onward (datamatters.sidley.com) (www.osborneclarke.com). Below we explore the main changes and their impact on medical devices and pharmaceutical use-cases.

Extended Timelines for High-Risk AI

Original AI Act: High-risk AI systems had phased dates. Annex III use-cases (e.g. remote biometric ID, certain critical classification) would be subject to obligations from *2 August 2026*; AI systems that are regulated products (Annex I – including AI as a medical device or safety component in an MD/IVD) were due from *2 August 2027* (datamatters.sidley.com). This tight timeline assumed the Commission would publish all needed standards and guidelines by summer 2026.

Enacted timetable: Under Article 113(c), Chapter III, Sections 1–3, except Article 6(5), apply from **2 December 2027** to Article 6(2)/Annex III high-risk systems and from **2 August 2028** to Article 6(1)/Annex I high-risk systems. These are fixed dates, rather than deadlines triggered by a Commission finding on standards. The implementation timeline separately identifies earlier literacy, prohibition, general-purpose AI and transparency milestones; the high-risk dates do not suspend every AI Act obligation.

Legacy Systems: Apply Article 111(2) separately to each system. For systems within that paragraph placed on the market or put into service before the relevant Chapter III application date, its transition is conditional on significant changes in design from that date and is without prejudice to the cited prohibitions. Establish classification, market-placement or service history and design changes before relying on this provision; it does not establish a company-wide audit exemption.

Implications

- **Plan against fixed dates:** Schedule the relevant high-risk compliance work for December 2027 or August 2028, according to classification.
- **Check other duties and transitions separately:** Review the earlier milestones and Article 111 rather than assuming that a standards delay postpones all obligations.

Conformity Assessment and Notified Bodies

Under the current AI Act, high-risk AI systems (including those embedded in regulated products) require **ex-ante conformity assessments**. But because sectors like medical devices already have their own conformity regimes (under the MDR/IVDR), there was ambiguity on whether a manufacturer would need two separate certifications.

Omnibus Clarification: The proposal explicitly confirms that **sectoral conformity takes precedence**. If an AI system is a medical device or part of one, then **the MDR/IVDR conformity procedure suffices to cover both the device and any embedded AI high-risk requirements (datamatters.sidley.com) (www.arnoldporter.com)**. Put differently, a manufacturer can incorporate the AI Act's substantive obligations (data governance, risk management, documentation, transparency, human oversight, robustness etc.) into the existing technical documentation required by the MDR/IVDR, rather than undergoing a duplicate "AI-only" audit (datamatters.sidley.com). The same goes for quality management: a single QMS (as required under MDR/IVDR) may be extended to meet the AI Act's requirements (datamatters.sidley.com).

This harmonization was a key industry ask. Sidley notes: "the AI Omnibus confirms that the AI Act's substantive high-risk requirements which are not covered by the MDR and IVDR … do not have to be addressed through a standalone AI-only assessment" (datamatters.sidley.com). Instead, notified bodies designated under MDR/IVDR will assess the AI parts in the course of the device certification. This saves substantial time and effort. For example, a manufacturer of an AI imaging software (a class IIb device) will not need to hire two different notified bodies for separate audits – one for MDR and one for the AI Act.

Streamlined Notified Body Process: The Omnibus also streamlines the *designation* of conformity assessment bodies. It allows a combined application and single assessment procedure for bodies seeking to be designated under both the AI Act and the relevant product legislation (www.osborneclarke.com) (www.arnoldporter.com). Moreover, existing MDR/IVDR notified bodies have transitional relief: they have 18 months after the Omnibus enters into force to apply for AI Act designation (www.osborneclarke.com). These changes should help *alleviate* the current shortage of EU NBs with AI expertise when the original deadlines drew near.

Implications:

- **Reduced Duplication:** MedTech companies benefit from one-stop conformity. Instead of separate documentation and audits, only one comprehensive procedure is required. Medical device manufacturers can integrate AI asset management into their ongoing quality and certification processes (datamatters.sidley.com) (www.arnoldporter.com).

- **Faster Market Access:** A single NB audit means fewer delays. An Arnold & Porter advisory highlights that “manufacturers of AI-enabled medical devices … should [be able to] reduce duplication” and that this will “help accelerate the availability of suitably designated notified bodies” (www.arnoldporter.com).
- **Continued Complexity:** Companies must still ensure they meet all AI Act obligations. The integration clarifications do not reduce substance; AI criteria (e.g. human oversight, data quality) must still be satisfied. It simply means compliance tasks can be bundled together. Careful project planning is needed to incorporate AI risk management into the standard conformity workflow.

Real-World Testing and Regulatory Sandboxes

The amended Article 60 covers real-world testing outside sandboxes of Annex III high-risk systems and systems covered by the legislation in Annex I, Section A. It preserves applicable Union and national product-testing law and required ethical review.

- **Real-World Testing:** A hypothetical hospital test remains subject to applicable Union and national product-testing law, required ethical review and Article 60. Its conditions include a testing plan submitted for authority approval, registration, informed consent, qualified oversight and reversibility of AI decisions. Testing is not an exemption from applicable sectoral permissions or ethics review. Assess updates under the relevant modification rules: Article 43(4) requires a new conformity assessment for a substantial modification of an already assessed high-risk AI system. Incident tracking alone is insufficient.
- **AI Regulatory Sandboxes:** The proposal tasks the EU’s AI Office with establishing an **EU-level sandbox** by 2028, supplementing the national sandboxes already being set up. It also calls for better coordination and information-sharing among Member States’ sandboxes (www.osborneclarke.com). For multi-country or cross-border pharma/medtech products, this creates a unified framework for regulated pilot projects.

Implications: These provisions promote innovation. Companies can *safely iterate* high-risk life science AI systems with real users and data before full clearance. As one analysis puts it, expanded testing opportunities “strengthen regulatory sandbox” for life sciences firms (www.osborneclarke.com). However, access will require robust data protection: even within sandboxes or real-world tests, GDPR and medical confidentiality rules still apply. Firms should use these mechanisms to refine AI models (checking for bias, reliability, integration issues) but must continue liaising with ethics boards and DPAs.

AI Literacy and Other Administrative Changes

Several smaller but notable elements of the Omnibus simplify compliance:

- **AI Literacy (Art.4):** Amended Article 4(1) requires providers and deployers to take measures supporting AI literacy among staff and others operating or using AI on their behalf, taking account of their knowledge, experience, education, training, use context and affected people. It removes the requirement to guarantee a specific level for an individual; it does not abolish the duty. The Commission confirms that national market surveillance authorities supervise and enforce Article 4.

- **SME/SMC Relief:** Do not infer eligibility for a simplification from employee numbers alone. The Commission's description of small mid-caps includes fewer than 750 employees **and either turnover up to €150 million or total assets up to €129 million**. Confirm qualification under the particular measure before relying on simplified documentation or penalty treatment.
- **Registration of Non-High-Risk AI:** Article 49(2) requires a provider, or its authorised representative where applicable, to register itself and an Annex III system it concludes is not high-risk under Article 6(3), before market placement or putting into service. Ordinary low-risk administrative tools should not be conflated with that specific exemption category.

Internal AI governance should reflect the duties that actually apply. The Article 4 literacy obligation remains, and the Article 6(3) classification exemption does not remove Article 49(2) registration. These provisions do not support a general recommendation to reduce governance resources for ancillary systems.

Bias Detection and Use of Health Data

The original AI Act was not silent on bias processing: Article 10(5) already allowed providers of high-risk AI systems exceptionally to process special categories of personal data where strictly necessary for bias detection and correction, with safeguards, as reflected in Recital 70. Article 4a(1) carries this narrowly conditioned permission forward. Its safeguards include demonstrating that other data cannot effectively achieve the purpose, security and access controls, restrictions on reuse and transfer, deletion requirements, and records explaining strict necessity.

Article 4a(2) extends permission to providers and deployers of other AI systems and models, and deployers of high-risk systems. Processing must be strictly necessary to detect and correct biases likely to affect health and safety, negatively affect fundamental rights or lead to prohibited discrimination, and all paragraph 1 conditions and safeguards apply. Paragraph 2 creates no obligation to conduct bias detection and correction.

Implications: Assess any proposed use of patient data for bias detection and correction against Article 4a's strict-necessity test and cumulative safeguards. The provision is purpose-limited; do not treat it as unrestricted permission to retrain models on patient data. Document why synthetic or anonymised data cannot effectively achieve the bias-processing purpose.

GDPR and Data Law Changes

Alongside the AI Act amendments, the **Digital Omnibus Regulation** proposes targeted tweaks to data protection and digital laws, many with direct relevance to health data and AI development in life sciences. We highlight the principal ones:

Redefining Personal Data (Pseudonymisation)

The original Commission proposal sought changes concerning when data may be treated as non-personal for a particular entity (Parliament's proposal summary). The EDPB and EDPS opposed the proposed narrowing. However, the Council's 21 October 2026 mandate maintains the current personal-data definition and instead

introduces a provision on pseudonymisation and identification.

Implication: The broader data Omnibus remains pending. Neither the original Commission proposal nor the Council mandate establishes an enacted pseudonymisation exemption. Companies should not assume that pseudonymised patient scans or trial datasets fall outside the GDPR on the basis of these proposals.

Scientific Research Exemptions

The GDPR contains Article 89 on research, but its scope has been deemed unclear. The Omnibus proposal aims to harmonize and expand the research carve-out:

- **Definition of Research:** It would specify that “scientific research” includes essentially all academic and non-academic research, including projects funded by industry (www.arnoldporter.com). This explicitly counters Member State ambiguities.
- **Legal Basis:** Health-data research needs both an Article 6 legal ground and an applicable Article 9 derogation. Legitimate interests under Article 6(1)(f) alone do not satisfy the special-category requirement.
- **Residual Data Proposal:** The pending GDPR proposal describes a narrow derogation for residual special-category data, with minimisation and output-disclosure safeguards. It should not be treated as general permission to collect patient health data intentionally for AI training or as interchangeable with the AI Act’s separate bias-processing provision.
- **Transparency Exemptions:** The Omnibus would create an exemption from some information duties when data is collected directly for research and providing notice is impossible or disproportionately difficult (www.arnoldporter.com). For example, long-term biobank research or retrospective analyses could avoid contacting thousands of subjects.

Implications: A DPIA, safeguards and an objection mechanism do not replace the Article 6 ground and applicable Article 9 derogation required for health-data processing. Establish both before using patient data for internal analysis or AI research. Do not treat pending Omnibus research proposals as permission to bypass the applicable consent or statutory requirements.

Data Protection Impact Assessments and Breach Reporting

The Omnibus includes practical streamlining:

- **Uniform DPIA Lists:** The proposal tasks the EDPB with creating *EU-wide white/black lists of processing operations* that require Data Protection Impact Assessments (www.arnoldporter.com). For multinational pharma conducting similar AI projects in different countries, this could prevent conflicting national DPIA decisions (a common headache). The Omnibus would also allow these lists to be updated by the EU regulators to reflect new technology, ensuring consistency.
- **Breach Notification Proposals:** The Commission proposes a 96-hour GDPR authority-notification deadline and a common template; this is a proposed amendment, not an enacted extension or a general permission to postpone notification with a lead authority’s approval. Apply the GDPR currently in force.

For incidents within NIS2's reporting scope, ENISA identifies a 24-hour early warning and a 72-hour incident notification. A shared submission mechanism must not be treated as merging those substantive reporting clocks.

Implications: The Council's 21 October 2026 mandate proposes a national reporting entry point in each Member State instead of the Commission's proposed EU-level single entry point, alongside an EU information point. This remains a negotiating position. Map each incident to the duties and deadlines that currently apply.

ePrivacy and Cookies

The original Commission proposal included the following privacy changes; the broader data Omnibus remains pending (proposal summary; Council mandate):

- **Consent Fatigue:** To combat endless cookie pop-ups, the directive would push for one-click consent and machine-readable preference signals (www.edpb.europa.eu). Websites (including health portals or medtech info sites) could rely on browser privacy dashboards instead of custom banners. The EDPB/EDPS *welcome* this "machine-readable choices" approach (www.edpb.europa.eu), expecting it to simplify compliance for online services (pharma marketing sites, patient apps etc.).
- **Biometric Authentication:** The pending data Omnibus proposes a derogation for biometric authentication where the verification means remain under the individual's sole control (www.edpb.europa.eu). This could facilitate fingerprint or face-ID login to patient apps or clinical portals. The watchdogs support this limited exception, noting its potential utility in secure health platforms.

For pharma and medtech websites and connected devices, the Council's 21 October 2026 mandate keeps cookie and other online-tracking rules in the ePrivacy Directive. The broader data Omnibus remains pending; the Council mandate is a negotiating position, not enacted law.

Other Data Laws (Data Act, DGA, etc.)

The omnibus also streamlines the wider "data acquis":

- **Data Governance Act (DGA) and Data Act:** The proposal *repeals* overlapping instruments (including the DGA and Open Data Directive), folding them into an updated Data Act (www.arnoldporter.com). While largely outside pharma's core business, this could affect how companies share industry data and use public research data. Importantly, proposed modifications limit B2G data access (>public emergencies only), relieving companies from broad mandates to hand over their data to governments except in crises.
- **Altruistic Data:** The Omnibus maintains incentives for data altruism organizations but underlines strong governance. Pharma collaborations like health data trusts would fall under these rules. Any expansion of data intermediaries will require careful due diligence to ensure patient trust.

Pharma companies should monitor Data Act changes insofar as they engage in data-sharing consortia, or use public datasets for AI training. Ensuring compatibility with GDPR (a priority of the EDPB/EDPS (www.edpb.europa.eu)) remains crucial: even if the Data Act grants use of certain data, GDPR legal bases still apply to personal data.

Industry Perspectives and Case Studies

To gauge the **practical impact** of these proposals, it helps to consider concrete examples:

- **Clinical AI Service (Hypothetical):** Consider a startup offering AI analysis of radiology images to hospitals. Establish the system's classification: Article 6(1) requires both the covered product or safety-component connection and a required third-party conformity assessment. Before any hospital test, establish the applicable testing permissions and safeguards. Before processing patient images, establish an Article 6 ground and applicable Article 9 derogation; legitimate interests alone are insufficient. No company-size relief or patient-data processing permission should be inferred merely from this hypothetical description.

Nonetheless, companies must remain proactive. The Omnibus does not eliminate regulation – it reorganizes it. Life sciences firms should map out all intersecting rules (AI Act, MDR/IVDR, GDPR, HIPAA/clinical trial regs) to ensure the new reliefs are leveraged properly. The message from advisors is clear: **cautious preparation** is needed. Many Omnibus provisions remain to be negotiated, as the European Parliament and Council may amend or narrow them (www.arnoldporter.com). Hence, while the Omnibus promises simplification, firms should continue preparing for full compliance under the existing framework until changes are finalized.

Data, Evidence and Analysis

The Digital Omnibus is driven by both qualitative feedback and quantitative analysis. The Commission's impact assessment estimates "at least €5 billion in administrative cost savings for businesses by the end of the Commission mandate in 2029" from the Omnibus measures (eur-lex.europa.eu). This figure includes streamlining data and AI rules; another €1 billion could be saved via other related reforms (in IP and other domains) (eur-lex.europa.eu). For sector context, the October 2024 Medical Technology feature attributed an estimate of around **7,754 European healthcare companies with AI exposure** to GlobalData's companies database; this is not a verified-adoption count. Even a few percent reduction in bureaucratic cost per company can thus translate to substantial GDP gains.

Econometric modelling in the Commission's Staff Working Document also breaks down the savings from specific simplifications. For AI literacy, the enacted Article 4 retains measures supporting staff literacy and removes a guarantee of an individual level; estimates based on abolishing the duty should not be presented as savings from the enacted rule. Aligning GDPR/NIS2 breach notifications is shown to save companies from redundant reporting (Annex IV, not shown here). A senior EU official noted that the entire digital package, including wallets and other tools, could "unlock another €150 billion in savings for businesses each year" (digital-strategy.ec.europa.eu) – although that figure mainly refers to broader digital identity solutions, it underscores the scale of potential efficiency gains.

On the flip side, regulators emphasize the *risks* of over-simplification. The EDPB/EDPS Joint Opinion (Feb 2026) welcomes many Omnibus goals but repeatedly warns against undermining rights (www.edpb.europa.eu). For instance, they support raising breach notification thresholds (saving administration) (www.edpb.europa.eu), yet "strongly urge" co-legislators to reject any changes that would improperly narrow the GDPR's scope (www.edpb.europa.eu). This tension – simplification *vs.* protection – is at the heart of the debate.

Academic and industry experts have similarly weighed in. Health IT analysts note that **AI adoption in Europe is soaring**. A 2024 report found some *1,752 AI-focused startups* continent-wide, with the health sector growing rapidly (www.pharmaceutical-technology.com). Hiring data shows pharma/health jobs in AI rose even while others plateaued (www.pharmaceutical-technology.com). This growth context underscores why the EU views regulatory agility as vital. Yet, surveys of medtech CEOs (e.g. by MedTech Europe) caution that regulatory fragmentation remains a concern. Their 2025 consultation response emphasized that "horizontal digital legislation [must be] aligned" to allow innovation to "translate efficiently into safe and effective technologies for patients" (www.medtecheurope.org). The Omnibus directly addresses this call by aiming for *legal coherence* – for example, by explicitly aligning AI with medical device law (datamatters.sidley.com).

In terms of future impact, if the proposals are adopted largely as-is, it marks a shift towards more **agile, impact-driven regulation** in the EU. The EU has often been seen as strict and rigid on digital tech; the Omnibus signals a recognition that rules must evolve in light of implementation realities (www.europarl.europa.eu). Life sciences companies should thus integrate these legislative trajectories into their 5- to 10-year strategies. R&D pipelines, data governance policies, and compliance budgets may need adjustment. Those who anticipate the new timelines and tooling (e.g. sandboxes) can gain a competitive edge, while those who assume old deadlines remain in force risk misallocating resources.

Discussion and Future Directions

The **Digital Omnibus** arrives at a moment of overlapping transformations in EU life sciences regulation. Besides the digital package, the EU has signalled upcoming revisions to the MedTech regime itself (a "MDR/IVDR Relief" proposal in December 2025) and continued evolution of health data frameworks (e.g. the upcoming Health Data Space). Together, these indicate a broad desire to make compliance *more realistic for innovation-intensive sectors*.

Key takeaways for stakeholders:

- **Regulators' stance:** Both the Commission and legislative bodies acknowledge industry pain points. EU Council conclusions in March/June 2025 explicitly demanded a "simplification and better regulation agenda" for digital rules (eur-lex.europa.eu). MEPs have drafted amendments (likely to become law) that emphasize avoiding overlap and burden on SMEs/SMCs (www.europarl.europa.eu). At the same time, the Parliament's think-tank warns simplification must not "upset the fragile equilibrium" of rights protections (www.europarl.europa.eu). In negotiations, expect carefully negotiated wording intended to keep any easing strictly technical.

- **Industry adjustments:** Companies should **audit their portfolios** to identify which products/systems are affected. For each AI-enabled product, firms should recalc its risk category and new compliance deadline. They should also prepare for integrated conformity: ensure their Quality Management System can absorb AI Act requirements alongside MDR/IVDR ones. For pseudonymisation planning, the Council's 21 October 2026 mandate maintains the current personal-data definition; do not assume the pending data Omnibus creates a broad exemption for pseudonymised patient data.
- **Use of sandboxes and guidance:** Life sciences innovators should engage with EU-level sandboxes and provide sector-specific feedback during ongoing consultations. For example, the Staff Working Document indicates forthcoming sectoral guidance from the AI Office on research exemptions (www.osborneclarke.com). Companies developing cutting-edge AI in medicine should be vocal about their practical needs during guideline drafting.
- **Investment and Innovation:** The cost savings estimated (billions in aggregate) could be reinvested in R&D. The European Commission anticipates that firms will spend "more time innovating and scaling-up" instead of paperwork (digital-strategy.ec.europa.eu). If the Omnibus does indeed reduce administrative drag, it may accelerate deployment of AI therapies, personalized medicine, or next-generation diagnostics.

Future Risks and Watchpoints:

- **Legislative load balancing:** The Omnibus is explicitly horizontal, but life science companies also face tightened health-sector rules (e.g. stricter MDR/IVDR timelines, clinical trial regulations). There is a risk of oscillation between tightening in one area and easing in another. Strategic alignment between health-specific law and digital law will be crucial.
- **Scope of "simplification":** The Commission's approach prides itself on preserving objectives. However, practical disputes will arise. For instance, defining when AI model updates count as "significant design changes" (triggering recertification) will be contentious (www.arnoldporter.com). Similarly, what exactly qualifies as bias mitigation "incidental processing" under GDPR is nebulous. Companies will need careful legal interpretation, potentially requiring case-by-case coordination with authorities.
- **Global context:** The EU is not alone in adjusting AI rules. Variants of "regulatory sandboxes" and standard-setting initiatives are emerging worldwide (e.g. US FDA's AI action plan, ISO standards). Alignment or divergence with international norms will affect market access. A nimble EU regime could set a benchmark, but excessive caution from data regulators (EDPB/EDPS) could conversely hamper predictability.

Outlook: Overall, the Digital Omnibus marks an important evolution in EU policy: from one-size-fits-all to **contextual regulation**. For pharma AI and medical devices, the shift recognizes the sector's complex dual regulation. The ability to innovate in healthcare increasingly depends on data and software; Europe's success in digital health will partly hinge on how well these legislative tweaks are implemented. Moving forward, firms

should plan for a *transition period* (through 2028) where Omnibus provisions gradually take effect. Engaging with industry associations (EFPIA, MedTech Europe) and regulators will help ensure the final laws strike the right balance.

Conclusion

The EU's **Digital Omnibus Simplification** initiative is a landmark effort to untangle regulatory burdens at a critical juncture for life sciences innovation. By reworking the AI Act, GDPR and related laws in tandem, the EU aims to ensure that compliance costs do not stifle the very advancement of safe, effective AI-driven therapies and devices. The proposed changes – extended timelines for compliance, harmonised assessments, clarified data rules – respond directly to concerns voiced by pharmaceutical and medtech stakeholders. They promise concrete benefits: faster market entry, unified quality systems, clearer research pathways, and billions of euros in administrative savings (digital-strategy.ec.europa.eu) (eur-lex.europa.eu).

However, these simplifications come with caveats. The EDPB and EDPS remind us that simplification should *not* dilute fundamental rights (www.edpb.europa.eu). Industry players must therefore approach the new regime with measured optimism. They should leverage easier processes and additional flexibility (e.g. sandboxes, bias analysis), but not ignore the enduring principles of patient safety and data protection. Risk managers and legal teams will still need to map each AI application through the intersecting rulebooks of EU law, ensuring that benefit of the Omnibus is fully captured without compliance gaps.

Looking forward, the Digital Omnibus is a stepping stone. The Commission's simultaneous "Digital Fitness Check" (launched Nov 2025) will examine the cumulative impact of EU digital laws, potentially leading to deeper reforms (datamatters.sidley.com). For now, life sciences companies should stay abreast of the Omnibus's legislative path, incorporate its timelines into planning, and continue engaging in the public consultation.

In summary, the Digital Omnibus initiative reshapes the EU compliance landscape for Pharma AI and Medical Devices. It reallocates the regulatory load – granting more flexibility and unifying processes – while reinforcing Europe's commitment to trustworthy innovation. If successfully implemented, it may well spur a new era where European healthcare providers and patients gain access to cutting-edge digital solutions more efficiently, without compromising on the high standards that underpin the EU's single market.

References: As detailed above, all key claims draw on official EU documents and expert analyses (digital-strategy.ec.europa.eu) (www.osborneclarke.com) (datamatters.sidley.com) (www.arnoldporter.com) (www.edpb.europa.eu). Specific citations are provided inline.

Source links

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