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Vital Signs

Our quarterly round-up of topics that
matter to you in the life sciences & healthcare sector

Winter 2025/26

Contents

Introduction

As the days grow shorter and the year comes to a close, we're delighted to bring you a festive winter edition of Vital Signs —your seasonal guide to the legal developments shaping the life sciences and healthcare sector. This time of year invites reflection as well as anticipation, and the industry is no exception: regulatory updates, policy shifts, and emerging technologies continue to evolve at a brisk pace, even as the world slows down for the holidays.

In this edition, we unwrap the latest insights on the UK Government proposal to create a new HDRS, including its potential impact on the sector, key milestones for 2026 and issues around privacy and cybersecurity. We also look back on the initial impact of the Procurement Act 2023, since it came into force in February 2025, and further changes expected for next year. For those with a focus on real estate, we offer practical tips and considerations for constructing life sciences facilities, given their complex design and technical requirements.

Finally, there's a chill in the air as we look ahead to the heightened risk environment brought by the new EU Product Liability Directive – the Ghost of Christmas Yet to Come.

Grab a warm drink, settle in, and enjoy this festive winter briefing.

David Bridge
Partner, Solicitor Advocate,
Co-Head Life Sciences & Healthcare
T +44 20 7367 3021
E david.bridge@cms-cmno.com

The New EU Product Liability Directive: What it Means for Life Sciences Companies

The EU's new Product Liability Directive[1] ("new EU PLD") marks the most significant overhaul of Europe's strict liability regime since 1985. It will apply to products placed on the market or put into service from 9 December 2026 and fully harmonises core rules across Member States. For Life Sciences companies and suppliers across increasingly digital and data-driven care pathways, the new EU PLD materially widens potential risk exposure, eases Claimants' evidential hurdles, and expands the pool of potential Defendants. These changes are likely to drive higher claim volumes, including follow-on and collective actions, and increase defence costs and early settlement pressures.

Scope: products, components, software and related services

The new EU PLD expressly brings software, including AI systems and embedded or stand-alone software applications, within the definition of a "product," alongside digital manufacturing files, raw materials, and electricity. It also treats certain digital services as "components" where their absence would prevent a product from performing one of its functions, provided they are within the manufacturer's control. In practice, a wide range of Life Sciences offerings now fall squarely within strict liability, including software as a medical device, device firmware and connectivity layers, clinical decision support tools, digital therapeutics, and cloud-connected monitoring services integrated with wearables.

Liability can also arise post-market where defectiveness results from software updates, upgrades, machine learning behaviour, related services, or the lack of necessary software security updates within the manufacturer's control. This is particularly salient for connected devices and AI-enabled products subject to lifecycle performance changes. Substantial modifications, whether hardware or software (including continuous learning), reset the limitation expiry clock as if a new product were placed on the market and shifts liability to the modifier if outside the original manufacturer's control.

A broader pool of potential Defendants across the supply chain

Beyond manufacturers and first importers, authorised representatives, fulfilment service providers, and, in some circumstances, distributors and certain online platforms can be held liable. If an EU-based liable party cannot be identified, distributors may be directly exposed if they cannot promptly identify an upstream operator in the EU. Components suppliers, including providers of software components integrated within a device, may also face direct claims. Joint and several liability applies, and liability in relation to injured persons cannot be limited or excluded. These channelling rules increase the number of available targets for Claimants and complicate indemnity and contribution dynamics within Life Sciences supply chains.

Defect: safety expectations, cybersecurity and regulatory context

Defect remains linked to the objective analysis of the safety that the public at large is entitled to expect or that is required by EU or national law, assessed in light of product presentation, intended and reasonably foreseeable use (including certain misuses), objective characteristics, instructions, and expected lifespan. For inter-connected and software-enabled products, courts will consider the reasonably foreseeable effects of other products and the product's ability to learn or acquire new features post-market. Cybersecurity now features expressly: vulnerabilities and failures to meet safety-relevant cybersecurity requirements can lead to a presumption of defect. Interventions by authorities and recalls are relevant circumstances to take into consideration for the defect test, though not automatic presumptions of defect.

Life-sustaining medical devices attract "particularly high" safety expectations. The new EU PLD also permits courts, in appropriate cases, to infer defect where a product belongs to the same series as one proven defective, reflecting the realities of batch or algorithmic common-mode failures.

1 Directive (EU) 2024/2853

Damages: psychological harm and data destruction, with low-value claims unlocked

Recoverable damage now extends beyond death, personal injury and property damage to include "*medically recognised and medically certified damage to psychological health*" and the destruction or corruption of data not used for professional purposes. The former is likely to feature in device-related claims concerning mental health impacts and in digital therapeutics contexts; the latter is relevant for consumer-facing health data stored on connected devices or apps.

The previous EUR 500 threshold for property damage has been removed; this opens the door to individualised low-value claims—fertile ground for collective redress.

Evidence and Burden of Proof: Powerful Presumptions and Disclosure

Three sets of measures substantially ease Claimants' evidential burden of proof:

— **Court-ordered disclosure.** Courts can order Defendants to disclose "*relevant evidence*" once Claimants show facts and evidence sufficient to support the plausibility of the claim. Production can extend to materials created *ex novo* by compiling or classifying "available" evidence, subject to proportionality and protection of trade secrets and privilege. While reciprocal disclosure is available, in practice, Defendants will undoubtedly bear the brunt of time and costs to satisfy a disclosure order.

— **Rebuttable presumptions.** Defect will be presumed where a Defendant fails to comply with disclosure orders, where there is non-compliance with mandatory product safety requirements intended to protect against the risk that materialised, or where damage was caused by an obvious malfunction during foreseeable use of the product. Causation is presumed where defect is established and where the damage is of a kind typically consistent with that defect.

— **Scientific or technical complexity.** Where, despite disclosure, it would be excessively difficult for the Claimant to prove defect and/or causation due to "*technical or scientific complexity*," courts must presume defect and/or causation if the Claimant shows that defect and/or the causal link is likely, taking "*all circumstances*" into account. The new EU PLD identifies innovative medical devices, machine learning, complex data or analytics, and complex causal pathways—such as links between pharmaceuticals or foods and health conditions—as paradigmatic examples. In practice, even Class I devices with sophisticated sensors, connectivity or embedded algorithms may meet the "*complexity*" threshold in the right factual setting.

These features, together with broader Defendant pools and expanded damage heads, materially increase the prospects of success for claims that historically struggled on proof, including claims involving medically-intricate causation theories and latent injury claims.

Time Limits and Defences

The core limitation period is 3 years from the date the injured person became aware, or should reasonably have become aware, of the damage, the defect, and the identity of the liable economic operator. The long-stop "expiry" period remains at 10 years from placing on the market or putting into service, but is extended to 25 years for latent injuries. Substantial modifications restart the expiry period on the modified product.

The new EU PLD allows Members States to derogate from the development risk defence.

The defence that the defect which caused the damage did not exist at the point in time the product was placed on the market/put into service is not available where the defectiveness is due to related services, software (including updates/updates), lack of necessary safety updates/upgrades, or substantial modifications of the product within the manufacturer's control. These carve-outs are especially pertinent for connected devices and AI-enabled products.

Litigation Outlook for Life Sciences

The new EU PLD is expressly consumer-protective and will encourage higher claim volumes, including high-volume, low-value claims and group or representative actions under the EU collective redress framework. Broader disclosure and presumptions will front-load defence costs and create early settlement pressure, particularly for legacy products or claims arising years after market entry. Expanded responsibility for post-market software and cybersecurity, and the ability to reach authorised representatives, importers and fulfilment service providers, make EU-facing supply chains more exposed and will encourage forum-shopping strategies by Claimants.

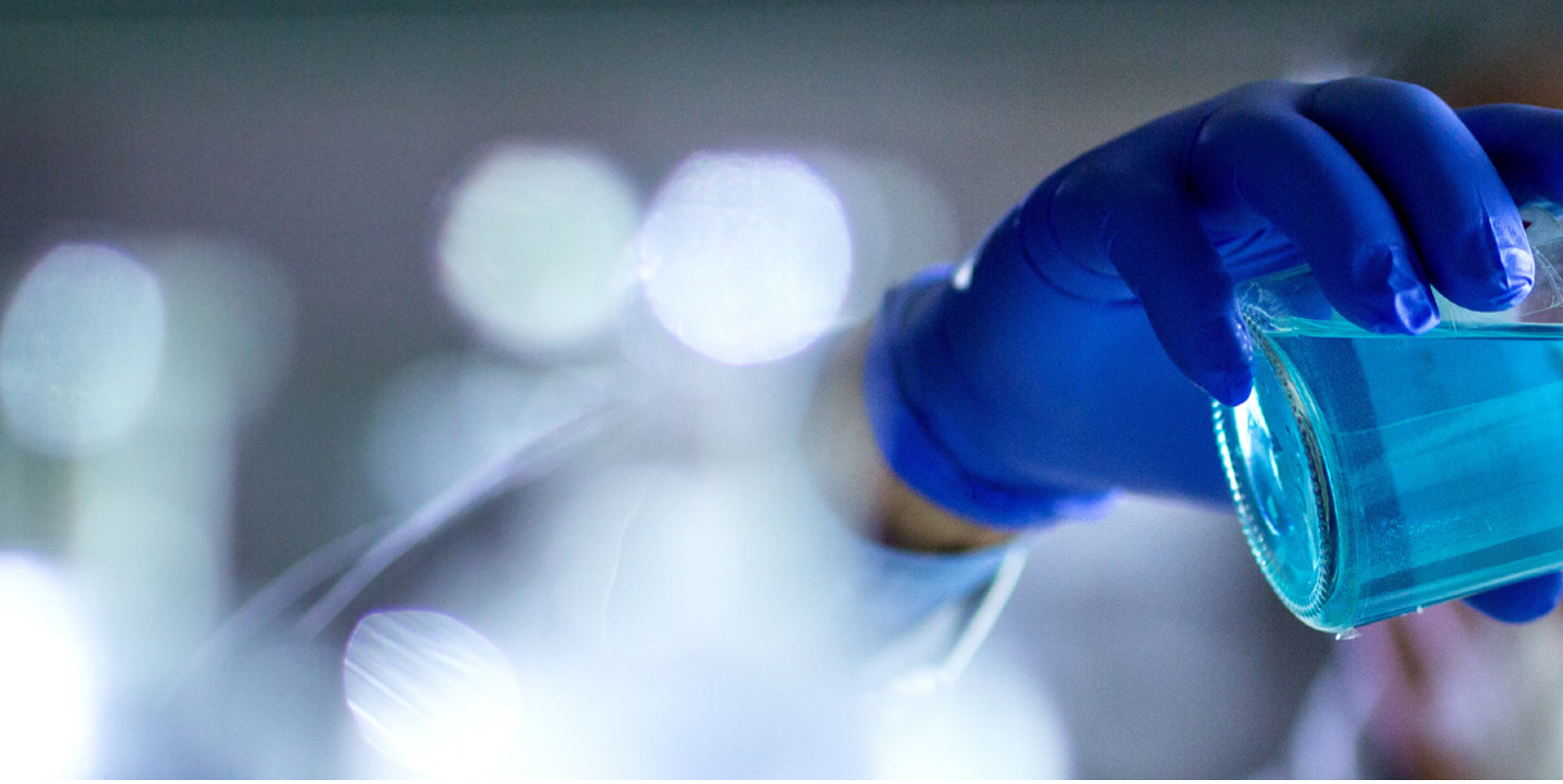
Practical Steps to Mitigate Risk

Life Sciences companies should recalibrate product governance to the new EU PLD's lifecycle and evidential realities. This includes robust pre-market design and risk-benefit files that squarely address foreseeable use and misuse; rigorous cybersecurity-by-design and update policies tied to safety risk; clear, consistent labelling and IFUs (noting that warnings cannot cure an otherwise defective design); and disciplined post-market surveillance, vigilance and field safety corrective action processes aligned to regulatory obligations.

For software-enabled and AI products, maintain reproducible models, versioning and audit trails, including data logging necessary to evidence safe performance and to respond proportionately to disclosure orders. Contractually, tighten supplier diligence and flow-down of safety, cybersecurity and update obligations; map authorised representatives, importers, fulfilment and distribution networks; and align indemnities and evidence-preservation duties with joint and several exposure.

Finally, reassess insurance coverage, reserves and incident response for data destruction claims and medically recognised psychological harm, and plan for Member State divergences on the development risk defence and on how courts operationalise the new presumptions and disclosure obligations.

Taken together, the new EU PLD heightens litigation risk across the Life Sciences sector. Companies that invest now in design controls, cyber-secure lifecycle management, documentation discipline, and supply chain governance will be better positioned to rebut presumptions, manage disclosure efficiently, and defend claims on the merits when the new regime takes effect.



Constructing Life Sciences Facilities – Key Considerations

Life sciences businesses need a range of real estate – from offices to specialist lab and production spaces. Much of the office space will be rented but it is common for the building of specialist technical spaces to be procured by life sciences companies themselves. Constructing these spaces can be challenging as the builds usually involve complex technical requirements and potentially significant adverse financial consequences if they go wrong or are delayed.

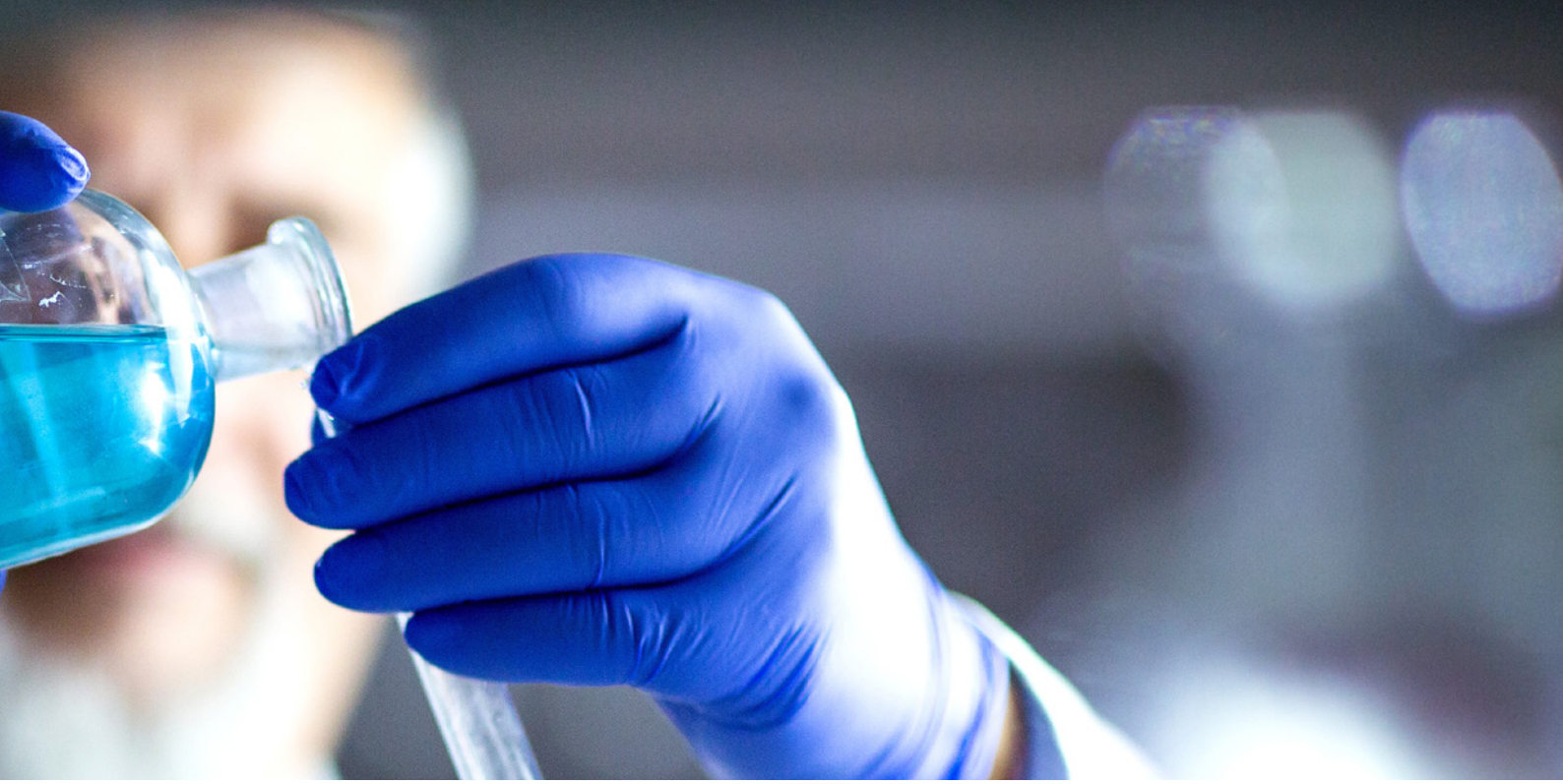
We set out here some of the key considerations to be aware of on the design and construction of such facilities.

Contract structure

One of the first things to consider is your procurement route. Many commercial buildings are built or fitted out under what's known as a "design and build" model where one contractor takes responsibility for both design and construction. However, because of the riskier nature of building laboratories and testing and production facilities, many contractors won't be willing to take on this risk or would add on a very high premium for doing so. As such, alternative models should be considered. This could be using a design and build approach for any shell and core (base) build, but with separate contracts for specialist fit-out works. This hybrid approach can work well but requires excellent and experienced project management to avoid delays and conflicts. You may also wish to consider alliancing arrangements which encourage and financially incentivise multiple parties to work together to avoid delays and promote conflict avoidance. Often a small incentive payment upfront can save significant delay costs.

Leveraging existing relationships

Many life sciences companies often have trusted suppliers for key pieces of equipment such as clean rooms and filling lines. Rather than leaving procurement to a contractor, you may want to contract directly with these suppliers to secure better terms and ensure quality. Again, this can add complexity and requires good project management to ensure all equipment arrives on time and doesn't delay the projects.



Delay damages

Most construction contracts contain delay damages – agreed financial amounts to be paid if the works complete late. In many types of construction contracts, these are set at a level to cover the losses arising from the delay. However, delays to production of pharmaceutical or other medical products can lead to significant loss of profit. Many contractors work on small margins and may not be able to shoulder all the risk of such losses. As such, you may wish to consider how best to mitigate losses or cover them in other ways. For example, there may be insurance products to cover business interruption, or there may be internal mitigations (e.g. not decommissioning older sites until the completion of the new facility).

Commissioning process

For highly technical facilities, it's not enough to just complete construction; it needs to be ensured that everything works as intended. Contracts should include a commissioning process before final payment is released. This will involve testing and validating equipment to ensure performance specifications are met, with clear criteria for final acceptance. The process usually also allows time for adjustments or remedial works if issues arise and may have agreed damages for any significant or non-rectifiable non-performance.

Insurances

Consideration will need to be given to insurance of the works whilst they are ongoing. This is often done through a specialist project insurance policy, particularly where multiple contractors and suppliers are all on one site at the same time. You should also consider suppliers' product liability insurance to cover the consequences of installing defective equipment and check that anyone responsible for providing design or services has adequate professional indemnity insurance to cover negligence.

Caps on liability

Most contractors will ask for a building contract to include an overall cap on liability to give a fixed maximum exposure in the event something goes wrong with the build. However, these are often tied to contract value or the value of insurances maintained by the contractor, not the value of the possible losses which could flow from the failure, e.g. inability to get a product to market. As with delay damages, other options such as business interruption insurance may need to be considered to make good losses.

All these issues can be addressed and risks mitigated with careful upfront planning in advance of starting works.

Public Procurement – Further Reforms in the UK and Europe

The long-awaited Procurement Act 2023 (PA23) came into force in February 2025. As we approach the end of the 2025, in this article we provide our initial reflections on the first 9 months of procurement under the PA23, and look ahead to further changes expected in 2026.

Reflections on the first months of the Procurement Act 2023

Transition
Public procurement in the UK is in a period of transition. Due to the transitional rules we have in place, it is clear that procurements will take place under the 'previous' procurement rules for many years to come. A significant volume of public purchasing in the UK takes place via framework agreements, including by the NHS. Despite being months into the new regime, it could be that suppliers of goods and services to the public sector are yet to participate in a procurement being run under the PA23.

For those operating in the health sector in England, the procurement landscape is complicated further by the NHS Provider Selection Regime. The NHS Provider Selection Regime has been in force since 1 January 2024 and covers the procurement of certain health care services by NHS England, ICBs, NHS trusts, NHS foundation trusts, local authorities and combined authorities.

Procedures
For those suppliers who have participated in a procurement under the PA23, they are not (yet) noticing a dramatic decrease in the length of time they need to spend on participation, or that the tendering rules are much simpler. Authorities are still getting to grips with the potential flexibilities of the new regime, and we do expect to see procedures designed in more innovative ways as authorities continue to build their confidence in navigating the new rules. Our early experience is that authorities may be more open to considering pre-market engagement and negotiation/ dialogue with suppliers/bidders as part of a procurement, which is welcomed. Suppliers should ensure they are monitoring pre-market engagement notices on Find a Tender and should engage in market engagement opportunities that arise.

Risk of exclusion
Suppliers are alive to the risks of the exclusion and debarment, and are seeking advice in relation to the application of the new and expanded exclusion grounds to their organisation. Of particular interest been the application of the exclusion grounds relating to poor performance and breach of contract, and the interaction of these exclusion grounds with the management of disputes under existing public contracts.

Using the Central Digital Platform
The Cabinet Office is trailing improvements to to the Central Digital Platform/Find a Tender Service (FTS) search functionality. We think any enhancements will be welcomed by suppliers. The Government Commercial Function (GCF) has published a series of videos to help stakeholders understand and navigate the CDP/FTS. The

GCF's latest video provides a short overview for suppliers of what they need to do to register as a consortium of two or more suppliers, which in the early days of the new platform seemed to cause some difficulty.

Further reforms in the UK

At the end of 2025, we await the outcome of the Government's consultation on further procurement reforms to ensure that public procurement is aligned to the Government's industrial strategy, improves domestic competitiveness, strengthens the UK's economic resilience and supports British businesses.

The formal response to the consultation is expected to be published in early 2026.

One consultation proposal that is of particular interest to suppliers is the proposed requirement on all contracting authorities to exclude suppliers from bidding on major contracts (+£5m), or explain why they have not excluded a supplier, if the supplier cannot demonstrate prompt payment of invoices to their supply chains. The Government seems focussed on flowing prompt payment rules down and through the supply chain. Businesses bidding for contracts over £5m should consider preparing for the possibility of this being introduced by adopting payment practices that comply.

Revision of the EU Public Procurement Directives

In the European Commission's 2024-2029 political guidelines, President von der Leyen announced a revision of the EU Public Procurement Directives. The reform of the EU Public Procurement Directives is intended to:

— Enable public bodies across the EU to give preference to European products in public procurement, helping to ensure EU added value and secure the supply of vital technologies, products and services; and

— Modernise and simplify the rules, while making public procurement a tool for strategic investment.

In its evaluation of the current EU rules, the Commission concluded that, overall, the EU public procurement framework lacks the agility, coherence and strategic focus needed to respond effectively to current and emerging challenges.

The Commission recently launched a 12-week consultation that will run until 26 January 2026, seeking input and evidence from stakeholders, including businesses, to inform the review of the EU Public Procurement Directives. Draft legislation is expected in Q2 2026.

While reform of the EU Public Procurement Directives will not result in further reform of the UK procurement rules, the changes will impact all organisations who deliver their goods and services to the public sector across the EU. We expect businesses to be particularly interested in the "Made in Europe" proposal, and life sciences businesses that supply to the EU public sector should consider responding.

UK Life Sciences Sector Plan: What the HDRS Means for Life Sciences

The UK government's Life Sciences Sector Plan (the "**Sector Plan**") sets out an ambitious vision to position the UK as a leading European life sciences economy by 2030 and third globally by 2035, behind only the US and China.

Central to this ambition is the Health Data Research Service ("**HDRS**") – a transformative initiative designed to create a secure, AI-ready platform that brings together genomic, diagnostic and clinical data at population scale.

Why the HDRS is needed

The UK's life sciences sector has faced various challenges in remaining competitive and attractive to investment, with limitations in the accessibility and quality of health data for research being one important factor. Currently, researchers cannot access all health data at a national level and variations in how data is collected and linked make analysis challenging and time-consuming. Multiple applications often need to be submitted to access different datasets, creating further delays.

The HDRS aims to address these issues by streamlining access to health data and providing a single, unified platform for researchers. Unlike many other modern health systems, which are often fragmented across multiple public and private providers (such as in the US), the UK benefits from the NHS, where each registered patient has a health record and, in many cases, patient data spanning their life time. This enables the HDRS to offer a large and consistent dataset for research and analysis, as well as the potential for longer-term trend analysis.

Creation of the HDRS

The Sector Plan proposes the creation of the HDRS, backed by up to £600 million investment from the UK government and the Wellcome Trust.

Key milestones include:

- Autumn 2025: appointment of the HDRS Chair and CEO;
- September 2026: the HDRS launches with a minimum viable product;
- December 2026: expansion to include new data assets;
- By 2030: full access to population-wide data assets, including:
  - general practice, hospital episode, prescribing/ dispensing and death registration data;
  - AI-ready datasets including linked pathology, radiology and genomic data.

This will enable a step-change in the scale and speed of research, supporting faster clinical trials and improved patient outcomes. The single platform will allow researchers to access and analyse comprehensive health data more efficiently, eliminating the need to submit multiple time-consuming applications to compare different datasets across regions.

By integrating health data, patients with target conditions can be identified more quickly and in greater numbers, supporting robust analysis of treatments versus outcomes across large datasets. This will likely accelerate the initiation of clinical trials and the development of new treatments, ultimately benefiting patients.

Key risk areas: privacy and cybersecurity

The potential impact of the HDRS on the sector is profound. It is expected to position the UK as a global hub for health data research, attracting international R&D and investment.

The HDRS intends to provide access to linked health data at national scale within a secure environment. However, expanding access to health data requires robust data protection and cybersecurity safeguards. Companies engaging with the HDRS should be prepared to navigate evolving compliance requirements and implement measures to mitigate risk.

The UK government has committed to embedding strong cybersecurity principles and maintaining safeguards while streamlining governance processes. Public trust will be critical to the HDRS's success.

Conclusion

The HDRS seeks to reshape the UK's life sciences landscape. By addressing systemic inefficiencies such as fragmented data sources, the HDRS aims to unlock the full potential of health data and attract global investment, accelerate innovation and deliver improved patient outcomes.

The next 24 months will be pivotal. With incorporation of HDRS as a government-owned company now underway and leadership appointments expected by Autumn 2025 (Baroness Nicola Blackwood was announced as the Chair on 25 November 2025, but as of the date of this article, the CEO has not yet been appointed), and the first HDRS services launching in 2026, the UK's ability to execute this vision may determine whether it achieves its ambition of delivering a globally competitive health data ecosystem.

Contacts

We hope you have enjoyed reading this festive briefing, if you would like to discuss any of the subjects in this publication with us, please do reach out to our Life Sciences & Healthcare Sector Co-Heads or the authors of the articles below.

David Bridge
Partner, Co-Head Life Sciences & Healthcare sector
T +44 20 7367 3021
E david.bridge@cms-cmno.com

Candice Blackwood
Partner, Co-Head Life Sciences & Healthcare sector
T +44 20 7524 6726
E candice.blackwood@cms-cmno.com

The New EU Product Liability Directive: What it Means for Life Sciences Companies

Elizabeth-Anne Larsen
Senior Associate - Solicitor Advocate
T +44 20 7524 6115
E elizabeth-anne.larsen@cms-cmno.com

Constructing Life Sciences Facilities – key considerations

Charlotte Eccles
Senior Associate
T +44 161 393 4753
E charlotte.eccles@cms-cmno.com

Public Procurement – Further reforms in the UK and Europe

Wendy Nicolson
Partner
T +44 20 7367 3725
E wendy.nicolson@cms-cmno.com

Emma Blundell
Senior Associate
T +44 131 200 74707
E emma.blundell@cms-cmno.com

UK life sciences sector plan: what the HDRS means for life sciences

Georgina Swift
Senior Associate
T +44 20 7367 2967
E georgina.swift@cms-cmno.com

Bonnie Clemence
Senior Associate
T +44 20 7367 2402
E bonnie.clemence@cms-cmno.com

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CMS Cameron McKenna Nabarro Olswang LLP
Cannon Place
78 Cannon Street
London EC4N 6AF

T +44 (0)20 7367 3000
F +44 (0)20 7367 2000

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