Smurfit Westrock | Adherence & Clinicals



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Dedicated service and support to Clinical Trial and Adherence focused partners

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In November 2025, as part of our global network, we officially opened the doors of our Horizon facility in Dublin - the world's first packaging site built exclusively for pharmaceutical patient medication adherence, regulated pharma packaging, and clinical trial services.

In March 2026, we welcomed industry leaders for an event centered on what matters most: **Patients - through the lens of Medication Adherence, and Clinical Trial Packaging Solutions.** The day delivered valuable and thought-provoking insights, culminating in a dynamic panel discussion and was followed by an exclusive tour of our state-of-the-art facility, giving attendees a firsthand look at where the future of clinical trials and medication-adherence packaging solutions is being shaped.



Bringing industry leaders together

Scan the QR code to access a copy of the industry presentations from the event.

Introducing Smurfit Westrock Adherence & Clinicals

Foreword by Brian Sheridan at Smurfit Westrock

As part of Smurfit Westrock, a global leader in sustainable paper and packaging solutions, Smurfit Westrock Adherence & Clinicals is a globally integrated business unit, delivering specialised support to the pharmaceutical, biotech and clinical trials sectors.

We do this by delivering innovative packaging solutions that strengthen clinical trials execution and enhance patient medication adherence throughout every stage of the drug life cycle.

Packaging plays a vital role in improving patient outcomes and by partnering closely with our customers, we develop tailored, patient-centric solutions designed to strengthen adherence, optimise packaging efficiencies, and support increasingly complex clinical and commercial supply chains. Care, consistency, innovation, expertise and a steadfast patient-first philosophy are at the heart of everything we do. These values have helped us build a strong leadership within the industry and it is what continues to fuel our passion. We believe what we do makes a difference.

While packaging is our business, developing solutions is our strength. Drawing on our team's extensive experience across clinical trials and drug launch programmes, we combine technical knowledge with innovative thinking to create packaging solutions that optimise supply chain and operational performance while supporting patient needs. This commitment to collaboration and continuous improvement is what our customers value and what we are proud to deliver.

We also believe strongly in contributing to the advancement of our industry. In addition to providing an overview of our business and capabilities, this brochure features insights from leading industry experts on key topics shaping the future of pharmaceutical packaging, including Digital Display Labelling and its Impact on the Clinical Supply Chain, Developing a Patient-Focused Approach to Packaging, and The Importance of Patient-Centricity: Advancing Innovation, Improving Outcomes.

You will also find an article from our technical director exploring the growing importance of materials science, testing, and validation in clinical trial supplies and secondary packaging. This section highlights the purpose-built white room facility at our Dublin Horizon Facility, specifically developed to support pharmaceutical cold chain storage and secondary packaging testing across temperature ranges from 2°C to 8°C, -25°C and with the capability to test down to -86°C. Combined with accelerated ageing chamber testing to assess long-term product stability, this investment represents a significant advancement in secondary packaging validation for clinical trials that we are pleased to share with you.

Thank you for taking the time to learn more about Smurfit Westrock Adherence & Clinicals. We look forward to the opportunity to work with you and to supporting your future clinical trial and pharmaceutical packaging needs.

Brian Sheridan, VP Global Adherence & Clinicals, Smurfit Westrock



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The importance of patient-centricity: advancing innovation, improving outcomes

By Avril Daly at Retina International and EURORDIS (Rare Disease Europe)

What does patient-centricity mean? What can it help achieve and why has it become essential in developing new treatments for areas where there are still major unmet medical needs? Why is it critical to advancing innovation and improving outcomes for patients, their loved ones and society at large?

I have worked as a patient advocate in rare disease and vision research for 25 years. Over that time, I have seen a major acceleration in innovation, with advanced therapies, including life-changing and potentially life-saving cell and gene therapies for conditions with very high unmet medical needs, becoming a reality. It is no coincidence that this has gone hand in hand with patient engagement and patient involvement in research.

Now regulators expect innovators to include patients in all aspects of their work from bench to bedside, concept to delivery.

Patients and their caregivers play a practical role in the development of therapies by participating in community advisory boards, where they advise on clinical trial protocol and how best to communicate with patient cohorts, taking into consideration their lived experience and what can be a burdensome process. Patients are also participants in data safety and monitoring boards where they monitor trials for their duration, working with clinical trial organisations and other experts.

In the rare disease space, this is even more important, as while individually rare the number of patients who live with one of over 6,000 rare diseases is 300,000 in Ireland, 30 million in Europe and 300 million globally.

Though disparate disease profiles, what often needs to be changed, is the seemingly singular approach to policy that treats them as the same. This is why over 1,000 patient organisations, including Retina International, are members of EURORDIS (Rare Disease Europe) to ensure that our collective voice is heard and the unmet needs of the community understood.

Adhering to evolving trial designs, from platform studies to multicentre trials, can determine whether a therapy succeeds or fails, whether disability is prevented or not, and in some cases, even the difference between life and death. As patient representatives, we are here to listen, to learn and – together with the industry – to lead the change we all need to make for a better future we can all share.



Avril Daly is an expert in health policy and strategic planning with over 28 years of experience working nationally, in Europe and internationally. In that time, she has worked on the development and implementation of health and research legislation in Ireland, as well as at above country level within the European Union, the World Health Organization and United Nations. Avril works as chief executive officer of the patient-led global umbrella organisation, **Retina International**, which represents the voice of charities and foundations concerned with the promotion of retina research, access to innovative solutions and related health policy in 43 countries. Avril was the chair of Rare Disease Ireland from 2006 to 2016 and rejoined the Board in 2024. Avril has held a Board Position in **Rare Disease Europe – EURORDIS** since 2009 and was appointed president in 2022.

Developing a patient-focused approach

By Deyana Mihaylova at IQVIA

In clinical trials, packaging and labelling represent the last and most critical line of communication between the study design and the patient. A patient-focused approach transforms these elements into essential safety tools that directly impact medication adherence, patient protection, data integrity and overall study success.

Clinical trial packaging must satisfy a web of global and country-specific regulatory requirements, from compliant label text and certified translations to approved packaging designs that support traceability and blinding. While these requirements are non-negotiable, regulatory compliance alone does not guarantee safe or correct medication use. Once investigational products leave the controlled clinical environment, packaging and labelling become the primary guidance patients and site staff rely on. If this guidance is unclear, impractical or poorly designed, adherence risks begin even before the first dose is taken.

Medication adherence can be affected by supply chain decisions made long before enrolment begins. Unclear dosing instructions, unreadable labels and impractical packaging formats can compromise correct administration. In trials where patients manage treatment at home, this is even more important.

Label text errors, such as incorrect dosing instructions or incomplete country-specific requirements, can halt medication dispensation, require emergency relabelling and delay patient enrolment. Vague instructions may lead to inconsistent dosing schedules, increasing patient-level risk and introducing variability into clinical data. Packaging failures such as incorrect kit quantities, unsuitable bottle caps or poorly applied blinding components can result in treatment interruptions, unblinding risks, medication loss and costly corrective actions. Glossy or coated label materials may prevent handwritten dosing instructions, requiring rework and causing treatment delays. Even blister label adhesion failures can expose medication unintentionally, leading to loss of product and disruption of patient treatment schedules.

Innovation in clinical trial packaging often begins with thoughtful customisation grounded in protocol understanding and patient needs. Practical solutions include separating country text between booklet and single-panel labels to ensure regulatory compliance without compromising readability and ensuring that label content is strictly aligned with the latest protocol version. Risk-based, cross-functional review processes are essential for identifying errors before they reach the patient.

Demo batch testing of label design and application can confirm readability, durability and usability under expected handling conditions. Careful selection of label materials supports easier patient interaction, while strategies such as colour-coding enable clear product segregation, accurate dispensing and improved traceability.

On the packaging side, accurate medication forecasting aligned with protocol requirements helps ensure correct quantities between visits, preventing supply gaps and the need for re-dispensation. Selecting packaging components based on indication, patient population, and usage environment supports safe handling and correct use. Thoughtful packaging design also safeguards blinding by ensuring visual and functional equivalence between treatments.

Ultimately, packaging and labelling are the final promise to the patient. It is the expertise of skilled clinical supply chain professionals that turns design into protection by anticipating risks, translating protocol intent into practical solutions, and ensuring that every decision supports patients, timelines and trust.



Deyana Mihaylova is an accomplished senior clinical supply chain manager at **IQVIA** with robust expertise in global clinical trial supply management across diverse therapeutic areas. With extensive knowledge in end-to-end supply chain planning, forecasting and logistics management, Deyana ensures seamless delivery of clinical trial supplies across complex, multi-regional studies.


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Discover the future now at our Horizon EXperience Centre

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Bringing secondary packaging in from the cold: the increasing need for testing and understanding the science of materials in the arena of clinical trial supplies and secondary packaging

Advancing cold chain assurance and mitigating risk: Smurfit Westrock's new white room sets a benchmark for testing of clinical trial supply packaging materials

By John Bratton at Smurfit Westrock

The clinical trial supply landscape is undergoing a significant transformation, driven by the rapid evolution of biologics, cell and gene therapies, and temperature-sensitive investigational medicinal products (IMPs). In response to these changes, Smurfit Westrock has taken a decisive step forward with the investment in a purpose-built white room at its Dublin Horizon facility. This state-of-the-art environment has been designed specifically to support pharmaceutical cold storage secondary packaging testing across a wide range of temperatures from 2 to 8°C, -25°C and down to -86°C. Coupled with an accelerated ageing chamber testing to look at long-term effects of product stability, this investment marks a major advancement in secondary packaging validation for clinical trials.

The expansion of cold chain requirements has introduced new complexities into clinical supply operations. Increasingly, IMPs must be stored, transported and used under tightly controlled temperature conditions to preserve efficacy and patient safety. However, despite these critical needs, there remains a notable gap in available data regarding the performance of secondary packaging under such extreme conditions. Smurfit Westrock's investment directly addresses this need, providing a controlled and validated environment where packaging designs can be rigorously tested to replicate real-world cold chain scenarios.

The Dublin Horizon facility's white room is configured to support both cold storage simulation and accelerated ageing and comprehensive stability studies specific to secondary packaging materials. These include, but are not limited to, moisture ingress analysis, adhesive bond performance, material integrity and colour stability – all essential considerations for maintaining both product protection and regulatory compliance. By evaluating how packaging behaves over time and under stress, pharmaceutical companies gain valuable insights into long-term performance, thus mitigating risk by enabling more robust and reliable clinical supply strategies.

A unique capability within the Dublin Horizon white room is the ability to conduct accelerated ageing studies – an essential tool in modern clinical trials supply strategy. Accelerated ageing is used to simulate the long-term effects of environmental conditions on packaging materials in a compressed time frame, enabling predictions of how secondary packaging will perform over the full duration of a clinical trial without the need to wait months or years to establish real-time data.

This capability comes at a critical time. As pharmaceutical pipelines increasingly shift towards complex, temperature-sensitive therapies, the demand for validated cold storage solutions has grown sharply. At the same time, sponsors and contract organisations face mounting pressure to reduce development timelines while maintaining the highest quality standards. Smurfit Westrock's white room capability set provides a practical solution to both challenges, enabling earlier and more accurate testing of packaging systems within the development life cycle.

A key differentiator lies in Smurfit Westrock's integrated, science-led approach. Rather than functioning solely as a packaging supplier, the company can support as a strategic partner – one that understands the unique requirements of the clinical trial supply chain. The Dublin Horizon facility exemplifies this philosophy, offering a world-leading infrastructure



that combines technical excellence with deep industry expertise. From initial concept design through to patient delivery, clients are supported by a team dedicated to ensuring packaging performs as intended under real-world conditions.

Importantly, the company recognises that packaging does not operate in isolation. The interaction between the sponsor, contract development and manufacturing organisation, and the patient through the medium of the packaging materials is complex, particularly when exposed to extreme temperatures. Variables such as condensation, material contraction, adhesive brittleness and structural integrity can all impact performance. Smurfit Westrock's testing capabilities are designed to evaluate these interactions holistically, ensuring that packaging solutions not only withstand target temperatures but also maintain their integrity throughout the entire duration of a clinical trial.

The ability to initiate stability testing earlier in the development process represents a significant advantage for pharmaceutical partners. By leveraging the white room environment, companies can generate critical performance data sooner, reducing uncertainty and accelerating decision-making. Faster access to validated stability results ultimately supports more efficient regulatory submissions and can help bring therapies to market more quickly – an outcome that benefits both sponsors and patients alike.

Equally important is the assurance of quality and compliance. All testing conducted within the Smurfit Westrock white room is supported by comprehensive pharmaceutical good practice documentation. This ensures that data generated is robust, traceable and suitable for regulatory review, facilitating a seamless transition through quality assurance processes. In an industry where documentation standards are stringent and scrutiny is high, this level of rigour provides essential confidence to stakeholders across the supply chain.

The opening of this facility underscores Smurfit Westrock's commitment to innovation and leadership within the clinical supply sector. By investing in advanced testing capabilities and aligning them with the evolving needs of pharmaceutical development, the company is redefining what it means to be a packaging partner. It is no longer sufficient to simply provide materials; today's clinical trials demand partners who can deliver scientific insight, technical assurance and end-to-end support.

With the Dublin Horizon white room, Smurfit Westrock has positioned itself at the forefront of this evolving landscape. The facility not only addresses current gaps in cold chain packaging validation but also anticipates future needs as therapies become increasingly complex and temperature sensitive. In doing so, it sets a new industry standard – one where packaging is fully integrated into the clinical development ecosystem, contributing directly to the safe, efficient and timely delivery of life-changing medicines.

As the pharmaceutical market continues to evolve, initiatives like this will play a critical role in enabling innovation and ensuring that clinical supply chains are equipped to meet the challenges ahead.



John Bratton is a technical director at **Smurfit Westrock**, recognised for his strategic mindset and ability to drive innovation in complex, evolving environments. With a focus on delivering long-term impact, John brings clarity, leadership and a forward-looking perspective to the challenges facing modern organisations.

Improving clinical supply chains with DDLs

By Alexander Debets, formerly at MSD/Merck

"Every medication kit needs a label… can we make an electronic one?"

From eLabels to digital display labels (DDL)

The shift towards digitally supported, patient-centric clinical supply chains gained momentum in 2015 with TransCelerate's eLabels workstream, which explored replacing or enhancing paper-based labels with electronic versions. Although the initiative concluded in 2021, engagement with health authorities was challenged by the reduced content on clinical supply paper labels.

Understanding DDLs

E-paper displays offer the ideal medium for DDLs. They are energy-efficient, lightweight, and highly readable, durable, and can display all essential regulatory information. DDLs can be battery-free, harvesting energy through technologies such as near field communication. Battery-powered however enables advanced functionalities, scrolling pages, advancing of electronic pages, interactive menus and integrated sensor technologies.

Industry collaborations and the DDL community of practice (CoP)

The DDL CoP – under the Clinical Supply Leadership Forum – brought together ten major industry players to work jointly on the DDL implementation, focusing on position papers, harmonised user requirements specifications, user experience, engagement with health authorities and a DDL life cycle management strategy.

A minimum viable product (MVP): the DDL vial

In collaboration with a pharmaceutical consortium, Smurfit Westrock, MSD and ECCT defined an MVP for DDLs tailored to clinical trial needs that had to be:

- Remotely updateable
- Capable of displaying multiple pages (scrolling)
- ERP (SAP)-integrated
- Cold-chain ready
- Compliant with all regulatory and quality requirements.

Pilots and preliminary outcomes

Starting in 2023, human factor studies were completed with a cohort of patients, nurses and pharmacists. Feedback demonstrated:

- DDL legibility and readability are comparable to paper
- Navigation of the display is clear
- Safe dose preparation could be performed.

By June 2025, pilot clinical phase 1 trials with DDLs were completed, revealing:

- No quality challenges
- >25% reduction in cycle time
- 80% clinical site satisfaction.

These results confirmed DDLs can streamline processes without compromising quality or compliance.

Challenges and benefits

While DDL implementation increases initial labelling and shipment costs, it significantly decreases drug waste, production complexity and inventory losses. The trade-off becomes particularly favourable in multi-country, multi-language and high-value trials – especially when expiration updates and stability assessments are ongoing.
In summary, the benefits clearly outweigh the costs, positioning DDLs as a transformative step for modern clinical supply chains.

Conclusion: the future is now

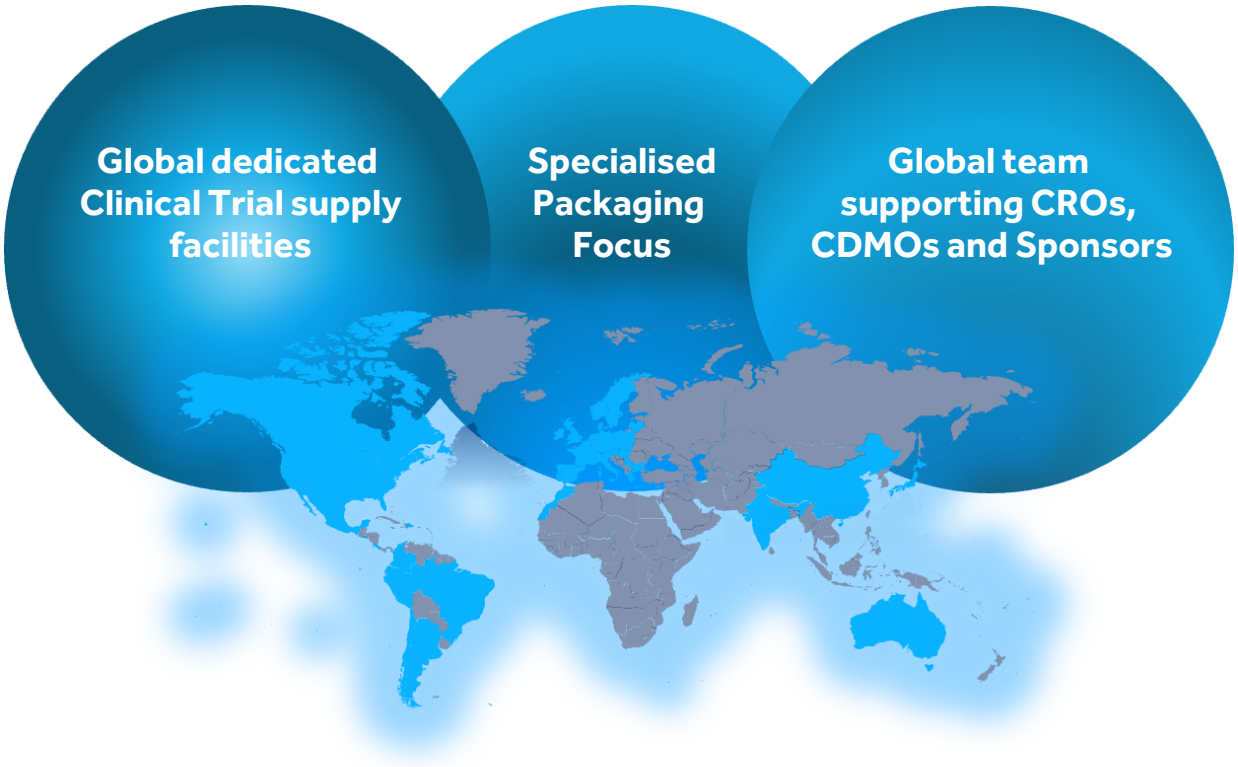
The clinical supply industry is entering a new digital era where packaging and labelling are no longer static components but interactive, data-driven interfaces. As we conclude with DDL products already entering the market: we are building a roadmap…but the future is now.



Dr Alexander Debets has more than 30 years of experience in analytical and pharmaceutical R&D, having held senior leadership roles at Organon, Schering-Plough and **MSD/Merck** in Analytical Development, Pharmaceutical Development and Clinical Supply. He has served as site head for development and manufacturing operations in Germany and Switzerland, including leading the successful transition of a site from R&D into commercial manufacturing.


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Our Smurfit Westrock Adherence & Clinicals team connecting with the global clinical trials community
London, UK - June
Outsourcing in Clinical Trials UK & Ireland
Shanghai, China - June
CPHI & PMEC China
Boston, N.A - June
Clinical Operations in Oncology Trials (East Coast)
Tokyo - June
ISPE Tokyo
Suzho, China - September
Outsourcing in Clinical Trials (OCT)
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Accreditations: ISO 9001, PS9000, ISO 14001 (Environmental Management System) and ISO 45001 (Occupational Health & Safety Management System)