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Time to First Patient

Introduction

Angela Clayton-Lea, CEO of Cancer Trials Ireland, opened the Spring DSSG Stakeholder Meeting on Daffodil Day by emphasising the unifying focus of the agenda: a relentless drive to reduce the time it takes to open clinical trials and get the first patient enrolled.

Ms Clayton-Lea outlined that quicker trial opening times benefit not only Ireland's international reputation as a research destination, but more importantly increase the opportunities for patients across the country to access potentially life-changing new drugs and treatments. She introduced the morning's speakers, who would address the theme from complementary perspectives: policy, industry, operational practice, and emerging technology.

The meeting took place on Daffodil Day, and Ms Clayton-Lea acknowledged the significance of the occasion and the presence of the Irish Cancer Society, whose partnership with Cancer Trials Ireland underpins much of the work discussed throughout the morning

Angela Clayton-Lea
Chief Executive Officer

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Daffodil Day 2026

Niki Warner is Research Partnerships, Programme Manager with the Irish Cancer Society

Ms Warner gave an overview of the Irish Cancer Society's partnership with Cancer Trials Ireland, describing it as a strategic and values-aligned collaboration with shared goals: getting more patients onto trials and more trials into Ireland. The Society invests over €1 million annually in Cancer Trials Ireland towards this purpose.

Ms Warner outlined the Society's advocacy role, including co-signing letters to ministers and supporting public-facing campaigns such as the Just Ask initiative. She referenced the Society's support for the PRO-ACT trial and efforts to secure Cancer Trials Ireland representation on the CTAC committee as examples of practical advocacy in action.

For the benefit of attendees, Ms Warner also highlighted the broad range of patient support services available through the Irish Cancer Society, including a support line, transport service, peer support programme, counselling - available both in person and online - daffodil centres in hospitals across the country, a night nursing service, patient education workshops, and a welfare and support team that assists patients with issues such as medical card access. She encouraged clinical staff to refer patients to the support line as the most effective starting point.

On research funding, Ms Warner drew attention to a number of open and upcoming calls, including the Cancer Research Networking Award (€5,000), the PPI and Research Award (€5,000), and the Patient Advocate and Cancer Research Award, which supports patient advocates in attending conferences and contributing to PPI. Further calls are expected in Q2 and Q4 2026, and researchers were encouraged to sign up to the Society's research newsletter or contact the team directly for updates.

Dr Niki Warner
Research Partnerships

Irish Cancer Society

The EU Biotech Act: Policy Context and Ireland's Role

John O'Neill is a Principal Officer at the Department of Health, the Health Research & Innovation Policy Unit.

John O'Neill provided an overview of the EU Biotech Act, a wide-ranging legislative package he described as complex in scope but critically important for the future of clinical research in Ireland and across Europe. While acknowledging the difficulty of covering such an extensive piece of legislation briefly, he focused on the elements most relevant to clinical trials and Ireland's position heading into the EU Presidency.

Mr O'Neill explained that the Biotech Act sits within a broader EU response to Europe's declining competitiveness in life sciences, a trend evidenced by falling global market share in clinical trials and the consistent movement of biotech investment and start-ups away from European stock exchanges. The Act seeks to address this through a unified framework for innovation, streamlined regulatory processes, and the mobilisation of approximately €10 billion in guarantees through the European Investment Bank.

From a clinical trials perspective, which accounts for an estimated 75 to 80 percent of the Act by volume, the regulation focuses on streamlining initial applications, substantial modifications, and ATMPs, and introduces provisions for risk-based approaches, regulatory sandboxes, a single gateway, and EU-harmonised templates. Mr O'Neill noted that approximately seven trials have already been assessed in a pilot under the FastEU initiative, with a report expected ahead of Ireland's Presidency.

Mr O'Neill acknowledged that the Act also encompasses amendments to directives on genetically modified mi-

John O'Neill
Department of Health

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croorganisms and the processing of human organs, making it a genuinely cross-departmental legislative challenge. He outlined the range of government departments and agencies already involved in Ireland's preparations and noted that this complexity would only deepen as the Presidency approached.

On national preparedness, Mr O'Neill confirmed that work was under way to establish CTAC (the Clinical Trials Advisory Committee) and an expression of interest phase is underway. He drew a clear line of alignment between what Ireland has been working towards domestically and the direction of travel at EU level: agile systems, innovative technology, and a risk-proportionate approach to regulation.

"The Biotech Act is very much aligned with what we were already trying to do here in Ireland — agile and responsive systems, innovative technology."

Streamlining Start-Up: The Cancer Trials Ireland Approach

Emer Mulvaney is the Contracts & Public & Patient Involvement Programme Manager with Cancer Trials Ireland.

Emer Mulvaney described how Cancer Trials Ireland had taken a structured look at its own start-up processes and introduced a dedicated start-up team to address needs around structure and ownership.

Before the team was established, start-up activities were distributed across multiple teams (contracts, operations, regulatory) with no single point of accountability for the full timeline. Work progressed sequentially rather than in parallel, meaning that delays compounded over time. Issues with contracting, GDPR compliance or study feasibility were often identified late in the process, when they were harder and more time-consuming to resolve.

The start-up team brought together contract, regulatory and operational functions, creating a single point of ownership from study concept through to site activation. Ms Mulvaney stressed that the intention was never to add a layer of process - any new step had to demonstrably reduce, not add, time overall.

The team's approach rested on three key shifts.

- First, earlier engagement: bringing contracting and operational input into the very first conversations with external groups, which allowed issues to be identified and addressed at the outset rather than mid-process.
- Second, standardisation: using model agreements and templates wherever possible to reduce negotiation cycles and speed up review.

Emer Mulvaney
Contracts & PPI

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- Third, moving from sequential to parallel working, so that contracting, regulatory review and study feasibility activity could progress simultaneously.

The results have been significant. Head agreements with external sponsors and funders dropped from a median execution time of 137 days before the team was established to 19 days in Q4 2025. Site agreement timelines fell from a median of 143 days to 73 days, with some sites now turning agreements around in as little as two and a half days. The overall timeline from SMG approval to site activation has also begun to reduce, with a 36 percent improvement in the period from contract receipt to activation.

Ms Mulvaney was candid that variability across sites remains a challenge. Different hospitals operate in different contexts, with different resources and processes - some highly linear and efficient, others more complex. She described this as one of the most significant difficulties when advocating for Ireland as a destination for new studies, and expressed the hope that the standard would continue to rise across all sites.

Looking ahead, Ms Mulvaney identified the period between NREC approval and site activation as an area with further room for improvement. She also reflected on a broader systemic question: Ireland currently waits for ethics approval before contracts can be signed, and for CTIS approval before the green light can be given, sequential dependencies that build delay into the system by design. She posed the question to the room: can those dependencies be re-thought?

"We have no choice but to get faster. We're a small country, we don't have a huge population and we're very expensive - but we're great, and we get on very well together. It's all possible."

Industry Perspective: Opening Trials in Ireland

Myra O'Dwyer is Country Clinical Operations Manager, Roche Products (Ireland) Limited.

Ms O'Dwyer brought an industry perspective to the question of trial start-up timelines, drawing on her direct experience managing global interventional trials and working to bring studies to Ireland. She delivered a data-driven presentation combining recognition of Ireland's strengths with a clear articulation of where processes need to change.

Ms O'Dwyer provided an overview of the CTIS (Clinical Trials Information System) framework, explaining that since its full implementation, all European countries now operate within the same regulatory timeline, with approval taking up to 106 days from CTIS submission. She noted that this has levelled the playing field and reduced the volume of protocol amendments, which had previously been a significant source of delay. However, she was frank that the real challenge now lies in what happens after CTIS approval.

Using a real example from a trial activated in early 2026, Ms O'Dwyer illustrated the gap between Ireland and the best-performing European countries. Germany and Spain activated their sites within four to six days of CTIS approval. Ireland took 51 days. She was clear that this was not a reflection of the commitment or capability of those working on the trial, everyone had been highly motivated and had worked hard, but rather a consequence of processes that had not yet adapted to the new regulatory environment.

She described how high-performing countries approach this differently: knowing that CTIS approval is essen-

Myra O'Dwyer
Roche Pharmaceuticals

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tially predictable once a study has been validated, they schedule their Site Initiation Visits in advance of final CTIS approval, complete document collection and green-light preparation in parallel, and are ready to activate the moment approval arrives. Contracts, in some cases, are signed before CTIS approval, a practice that Ms O'Dwyer acknowledged would raise eyebrows in Ireland, but which she presented as carrying minimal risk given the robustness of today's CTIS process & the Green light process to activate sites .

Ms O'Dwyer was clear about the reputational stakes. Performance metrics are tracked globally and fed into algorithms that influence which countries receive future studies. A poor metric, she noted, is harder to reverse than it is to avoid. She urged the room and sponsors to think about resourcing, training portals, and the volume of documentation required before activation as areas where forward planning could dramatically compress timelines.

She also acknowledged Ireland's genuine strengths: exceptional data quality, a strong national contract process, which she described as a model that Roche's global teams had actively praised, and talented, committed staff across the system. She closed with a call to action: if Germany, Spain, and Denmark can do it, Ireland can too.

"A bad metric - no metric is better than a bad metric. If you don't deliver on a trial and you're slow, that has a potential impact on getting future studies, across every therapeutic area."

Trials in HSE Hospitals: Progress and the Road Ahead

Racheal Bourke is the National R&D Lead for Legal & Data Protection Research Support Services, HSE

Ms Bourke outlined the work of the HSE's legal and data governance team within the National Research and Development office, a team she noted was eight years in the making and now moving into a new operational phase with the establishment of the National Centre Research Office.

Ms Bourke described a system that has made genuine progress but where significant structural gaps remain. She was direct in her assessment: Ireland has world-class medical talent and strong hospitals, but the administrative and governance infrastructure supporting clinical research has not kept pace. Too often, research nurses and clinical staff are expected to carry administrative burdens that would, in a well-resourced system, be handled by dedicated personnel. This takes clinicians away from the bedside and introduces inconsistency and delay across sites.

On ethics reform, Ms Bourke highlighted the implementation of a single ethics approval model through regional reference RECs, noting that the Dublin Midlands REC had already seen meaningful impact from this change. She described the problem that the new model aims to solve: a trial approved by one ethics committee should not be subject to different conditions when it moves to another site. Fragmentation in ethics processes is a symptom of a wider systemic problem, not a reflection of the quality of the work being done.

On GDPR, Ms Bourke questioned the narrative that data protection legislation is the primary source of delay. The issue, she argued, is not the legislation itself but inconsistency in how it is interpreted and applied across

Racheal Bourke
HSE

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sites. The solution is education, skill development, and clearer national guidance, rather than a relaxation of standards.

Ms Bourke outlined a range of practical tools and resources her team has developed or is developing: a national consent policy for research, standard templates for clinical trial agreements (commercial sponsor-hospital and commercial sponsor-CRO-hospital, with academic-sponsored templates under negotiation), a jurisdictional transfer assessment tool that provides a full risk report in approximately ten minutes across 56 jurisdictions, a national DPIA and data protection protocol for multi-site trials, and a suite of bite-sized data protection webinars available on HSELand.

She also flagged the imminent national rollout of an electronic research management system, with 38 additional staff coming on board, which she anticipated would bring greater visibility, accountability and standardisation across the system.

Ms Bourke central message was that the investment case for dedicated administrative staff in clinical research is straightforward. When the right support is in place, trials open quickly and run well. The return on that investment is a more attractive Ireland for international sponsors and ultimately, more patients on trials.

"We need to be brave enough to say yes, we need this investment because the return is that we become a more attractive country for sponsor companies, and that benefits patients."

Q&A session

The Q&A session surfaced a number of proposals and shared priorities.

On the question of signing contracts before CTIS approval - the practice already adopted in Germany and Spain, both Racheal Bourke and John O'Neill expressed openness to exploring a pilot approach in Ireland. Ms Bourke indicated that with the right governance in place and checks and balances completed up front, it was entirely feasible. She noted that in a previous role she had operated in exactly this way, with everything ready to go by the time ethics approval was received. Mr O'Neill noted that the risk-based thinking underpinning this approach was very much in keeping with the direction of the EU Biotech Act. Angela Clayton-Lea indicated that Cancer Trials Ireland would actively pursue this as a next step.

The question of consistency across sites was a recurring theme. Participants noted that the current variability, where some sites can turn around site agreements in days while others take months, is one of the most significant barriers to attracting multi-site trials. There was broad agreement that a national standard is needed, and that the Department of Health and the HSE have a role in setting and enforcing it. One participant suggested that a successful pilot at a single site could serve as an exemplar, with the Offices of the Regional Executive and the Department helping to mandate its rollout.

Resourcing was raised repeatedly. Participants echoed Ms Bourke's point that having the right administrative and contractual expertise on site, ring-fenced and properly funded, would transform the system. The comparison was made to other European countries where ring-fenced trial funding for roles such as research nurses is standard practice.

The absence of a national electronic health record was also noted as a significant disadvantage when trying to match patients to trials efficiently, and as an additional burden on already stretched teams. This point connected directly to the final presentation of the morning.

AI-Assisted Patient Matching: Evident Med

Kevin Barrett and his co-founder Rob Brown introduced Evident Med, an Irish company, formerly known as Genotrial, that has developed an AI-powered platform to help research teams identify eligible patients for clinical trials more efficiently.

Kevin opened by framing the problem: patient recruitment remains the single biggest challenge in clinical trials globally. Of the approximately 25,000 cancer trials actively recruiting worldwide, 60 percent will fail to meet their enrolment targets. Beyond the cost to sponsors, estimated at €60 billion annually, the human cost is significant: limited access to potentially life-saving treatments is associated with increased patient mortality rates of between 6 and 13 percent.

The core challenge, Kevin explained, is that even in 2026 the process of identifying eligible patients is largely manual. Research teams search through patient records - often fragmented across multiple systems, or still paper-based, without real-time visibility of where eligible patients actually are. This is time-consuming, error-prone, and unsustainable at scale.

Evident Med addresses this by integrating with whatever data sources exist at a given site (electronic health records, scanned paper records, pathology reports, radiology reports) and consolidating that information into a single searchable format. Using an AI model trained to read and interpret both structured and unstructured clinical text (studies suggest that up to 80 percent of the most important clinical information is held in unstructured text, even in advanced EHR systems), the platform surfaces a ranked list of potentially eligible patients for a given trial protocol based on its inclusion and exclusion criteria.

Kevin Barrett & Rob Brown, Evident Med

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Rob Brown demonstrated the platform, showing how a trial protocol pulled directly from the EU Clinical Trials Register can be uploaded to the system, which generates a structured criteria list and runs an overnight search across the site's patient data. The output is a ranked shortlist of patients with the best initial match, not a definitive eligibility determination, but a starting point that allows research teams to focus their time on the patients most likely to qualify, rather than spending hours manually reviewing records that may ultimately lead nowhere.

Kevin was emphatic that the platform is designed to support, not replace, clinical judgement. It reduces the administrative burden and surfaces the right patients faster; the clinical team makes the final assessment. He also stressed that data never leaves the hospital site, making the platform fully GDPR-compliant, a point that resonated strongly in the context of the morning's earlier discussions.

Evident is currently seeking one to three pilot sites in Ireland to begin measuring the real-world impact of the platform in terms of time saved and accuracy of patient identification, with a view to expanding from there. Angela Clayton-Lea encouraged interested parties to make contact through Cancer Trials Ireland.

Conclusions

The discussions reflected a system that is moving in the right direction, with genuine momentum behind the drive to reduce start-up times - but one that is also clear-eyed about the competitive pressures it faces and the structural changes still needed to realise its full potential.

Several clear priorities emerged across all presentations and discussions.

- **Process:** Ireland must aim to move from sequential to parallel working at every level of the system, within Cancer Trials Ireland, within hospital sites, and across the national governance framework. The German and Spanish model of front-loading preparation to achieve near-immediate post-CTIS activation should be the benchmark Ireland works towards. A pilot testing this approach in the Irish context was identified as a possible next step.
- **Consistency:** Variability across sites, in contracting timelines, ethics processes, administrative capacity, and GDPR interpretation, is one of the more significant barriers to attracting and retaining multi-site trials. A national standard, supported by central guidance and adequately resourced, is needed.
- **Resourcing:** Dedicated, ring-fenced administrative and research support staff are not a luxury, they are the infrastructure that makes the system work. The investment case is clear, and the return is measurable in trials won and patients enrolled.
- **Policy alignment:** Ireland's domestic reform agenda, from CTAC to the National Research Office to the ethics reform programme, is well aligned with the direction of the EU Biotech Act. As Ireland prepares to assume the EU Presidency in July 2026, there is an opportunity to shape the European conversation from a position of hard-won practical experience.
- **Technology:** Tools such as Evident Med's AI patient-matching platform represent a practical and near-term opportunity to address one of the most persistent bottlenecks in the system. The absence of a national EHR need not be a permanent barrier to progress if the right intelligence layer can be applied to existing data sources.

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