

Accelsiors



Issue #1

Connecting The Dots

Welcome to the New Accelsiors Newsletter: Connecting the Dots

Dear Partners, Investigators, Patients, and Future Colleagues,

In the fast-moving world of clinical research, it is easy to get lost in the data. We spend our days focused on the micro: the specific biomarker, the regulatory clause, the dataset. But sometimes, to see where we are going, we need to look at where we came from, and where the wider world is heading.

That is why I am proud to launch the new **Accelsiors Bi-Weekly Newsletter**.

We have designed this as a "living ecosystem" of ideas. A place where history, innovation, and practical application meet.

From the Past to the Future, We believe that drug development is a continuum. That is why every issue will feature our signature "**Molecule to Medicine**" column, tracing the historical roots of scientific breakthroughs, like the discovery of CRISPR or the first antibiotics. We then connect these stories directly to modern applications in our "**Reader's Digest**" section, showing how the "crazy ideas" of the past became the standard of care today.

Excellence in Execution: A successful trial requires trust, talent, and rigorous execution. To support you in these areas, we are introducing specific columns:

The Integrity Shield: Updates on Quality by Design (QbD), data security (NIS 2), and compliance.

Accelsiors in Action: A look at real-world case studies where our services helped clients overcome complex clinical hurdles.

The Patient Voice: Because ultimately, we don't treat data points; we treat people.

Talent & Tomorrow: A dedicated space for professionals and students shaping our industry's future.

The Clinical Pulse: A curated summary of the industry news that matters most.

Join the Conversation: Finally, this newsletter is a two-way street. In our new "**Open Forum**" section, we want to hear from you. Whether it is a question about a new regulation, feedback on an article, or a topic you want us to cover, this is your space to help shape the conversation.

At Accelsiors, we don't just execute trials; we accelerate the future. Thank you for being part of our journey. **Welcome to the first issue!**

Sincerely,

Mihaly Juhasz CEO, Accelsiors CRO

Molecule To Medicine - Stories From Drug Discovery And Development

Beyond the "Eureka": Why the Second Leg of the Race Matters Most History loves a "Lone Genius."

We love the image of the scientist shouting "Eureka!" in a bathtub or watching an apple fall from a tree. It suggests that innovation is a moment of lightning-strike inspiration. But anyone working in the life sciences knows the truth: Discovery is only the starting gun. The real race, the grueling marathon between a concept and a cure, happens in the development phase.

At Accelsiors, we specialize in that critical second phase. To illustrate why execution matters just as much as invention, we looked back at history. Here are five famous scientific breakthroughs where the "Pioneer" who found the spark was different from the "Developers" who built the fire.



1. The Antibiotic Revolution (Penicillin)

The Pioneer: Alexander Fleming (1928).

Fleming famously returned from a holiday to find a petri dish where mold was killing bacteria. He identified the substance as penicillin, published a paper, and then... hit a wall. He couldn't stabilize it or produce enough of it. He eventually moved on to other work.

The Developers: Howard Florey & Ernst Chain (1940s): It took a decade for this team at Oxford to pick up Fleming's baton. They did the unglamorous, difficult work of purification, chemical stabilization, and clinical testing.

The Lesson: Fleming found the molecule; Florey and Chain built the medicine that saved millions in WWII.

2. The Gene Editor (CRISPR)

The Pioneer: Francisco Mojica (1993)

Working in absolute obscurity in Spain, Mojica was the first to identify the "repeating" DNA patterns in microbes and realized they were an immune system. He even coined the name "CRISPR." Yet, few outside the field knew his name.

The Developers: Doudna, Charpentier, & Zhang (2012)

Years later, these teams figured out how to strip this mechanism from bacteria and engineer it into a programmable tool for human cells. They turned a biological curiosity into a biotech revolution.

3. The Diabetes Miracle (Insulin)

The Pioneer: Nicolae Paulescu (1921)

This Romanian professor published data on "pancrein," a substance that lowered blood sugar in dogs. However, his extraction method was crude and caused adverse reactions.

The Developers: Banting, Best, & Collip (1922)

While Banting and Best get the fame, it was the biochemist James Collip who was the unsung hero. He developed the method to purify the insulin enough to be safe for humans, taking it from a toxic extract to a life-saving therapy.

The Lesson: In drug development, efficacy means nothing without purity and safety.



4. The Glowing Tag (GFP)

The Pioneer: Douglas Prasher (1992)

Prasher cloned the gene for Green Fluorescent Protein (GFP), realizing it could revolutionize how we track cells. But funding dried up. He had to leave science and eventually took a job driving a shuttle bus to make ends meet.

The Developers: Chalfie & Tsien (2008)

Prasher gave his data to them for free. They successfully optimized the gene for use in other organisms. They won the Nobel Prize; Prasher was watching from the sidelines.

5. The Vaccine Speed Record (mRNA)

The Pioneer: Katalin Karikó (1990s-2000s)

For decades, Karikó insisted mRNA could fight disease. She faced demotions and rejected grants because the science was considered too unstable and risky.

The Developers: BioNTech & Moderna (2020)

When the global need arose, these companies utilized Karikó's optimized technology, combined it with advanced delivery systems (Lipid Nanoparticles), and scaled it up to treat billions. In the biotech world, there is a concept known as the "**Clinical Chasm.**"

This is the most critical juncture in a drug's lifecycle. Countless brilliant molecules, potential "Penicillins" or "Insulins", never reach the market, not because the science was bad, but because the path through clinical trials was too complex to navigate alone.

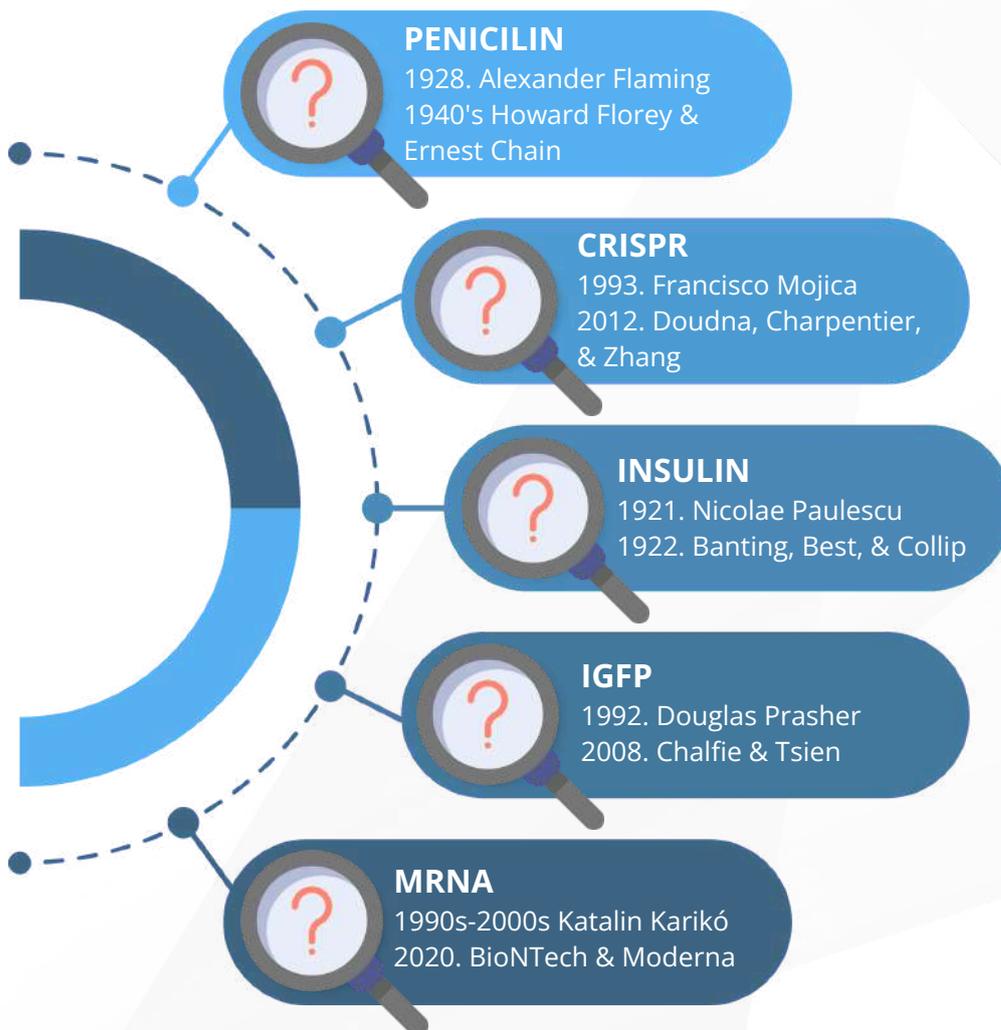
The stories above highlight a universal truth: **Discovery happens in the lab, but medicine happens in the clinic.** Just as Florey had to take the risk of administering Penicillin to his first human patient to prove it worked, today's biotech innovators face the daunting task of translating pre-clinical data into human results.

That is where Accelsiors CRO steps in

We view ourselves as the specialized "Developers" for the modern age. Your team has done the heavy lifting of discovery and pre-clinical development. You have the vision and the molecule. Our role is to take the baton for the most crucial leg of the race: **Clinical Development**.

At **Accelsiors**, we help you navigate the regulatory maze, manage complex patient data, and execute the rigorous trials necessary to turn a biotech asset into a market-approved drug. We bridge the gap between scientific potential and patient reality.

Your molecule is ready for the world. Let's make sure the world is ready for your molecule.



Raising the Bar in Quality, Data Protection, and Cyber Resilience

Over the coming months, Accelsiors is rolling out an integrated compliance initiative across three of the most influential standards impacting clinical research today:

- **ICH E6 (R3)** – the next generation of Good Clinical Practice
- **ISO 27001:2022** – the leading standard for information security
- **NIS2 Directive** – the EU's updated framework for network and information security

As a clinical CRO, our work is grounded in **patient safety, data integrity, and operational reliability**. Since 2020, we have been continuously strengthening our Quality Management System (QMS). This new series is the next step: aligning our quality, data protection, and cybersecurity practices into a single, robust framework that directly supports our sponsors and partners.

Over a series of 24 weekly articles, we will share how we are implementing these standards and, more importantly, what this means for **your trials, your data, and your patients**.



Pillar 1: ICH E6 (R3) – The Future of Clinical Quality

ICH E6 (R3) is the most significant update to Good Clinical Practice in many years. It reflects the realities of modern trials: decentralized designs, digital endpoints, complex data flows, and globalized operations. In this pillar, we will describe how Accelsiors is:

- Implementing a **risk-based quality management system (QMS)** to focus effort where it matters most for patient safety and data reliability.
- Strengthening **data integrity** practices across the full data lifecycle, from site source documents to eClinical platforms.
- Enhancing **patient-centricity**, including how we design, conduct, and monitor studies to minimize burden and protect participants' rights and well-being.
- Elevating **vendor oversight**, ensuring that laboratories, technology providers, and other partners operate to the same quality expectations.
- Applying R3's emphasis on **proportionality** to refine our **monitoring and auditing** approaches, more targeted, more efficient, and more transparent for sponsors.

For our clients, this translates into **more reliable data, more predictable quality, and clearer oversight** throughout the study lifecycle.

Pillar 2: ISO 27001:2022 – Protecting Clinical Information

Clinical research depends on the secure handling of sensitive data: patient information, trial results, and proprietary sponsor data. ISO 27001:2022 is the globally recognized standard for building an effective Information Security Management System (ISMS).



Our ISO 27001:2022 track focuses on:

- **Access controls:** ensuring that the right people have access to the right information at the right time and no one else.
- **Asset management:** classifying and protecting information assets, from databases and applications to physical records.
- **Physical security:** controlling access to facilities and critical infrastructure where trial data is processed and stored.
- **Supplier security:** managing and monitoring the information security posture of third parties involved in your studies.
- **Company-wide training:** fostering a security first culture so that every employee understands their role in safeguarding data.

For sponsors, our ISO 27001:2022 implementation means **greater assurance that trial data and confidential information are protected against loss, misuse, or unauthorized access**—from protocol development to final reporting.

Pillar 3: NIS2 – Securing Our Digital Operations

The NIS2 Directive raises the bar for cybersecurity in essential and important entities across the EU, including organizations operating in the healthcare and life sciences sectors. For a CRO, this is not just a regulatory requirement; it is central to protecting ongoing trials and ensuring operational continuity.

Within this pillar, we will outline how we are:

- Enhancing **incident detection and reporting**, enabling faster, more structured responses to potential cyber events.
- Strengthening our **supply chain security**, including evaluating and monitoring the cybersecurity posture of critical vendors and service providers.
- Reinforcing **business continuity and disaster recovery** measures to keep critical trial operations running even under adverse conditions.
- Elevating **governance**, with clear board level oversight and accountability for cybersecurity risk.

The result for our clients is **greater resilience**: reduced risk of disruption to your studies and clearer communication channels in the unlikely event of an incident.

Integrating the Three Pillars – A Unified Framework for Our Clients

Rather than treating ICH E6 (R3), ISO 27001:2022, and NIS2 as separate projects, we are integrating them into a **cohesive operational framework**. In the final part of our series, we will share how we:

- Address **integration challenges** across quality, security, and IT.
- Use **simulated scenarios (tabletop exercises)** to test our readiness and refine processes.
- Build mechanisms to **sustain compliance** as standards, technologies, and trial models continue to evolve.

This integrated approach is designed to give you **consistent quality, transparent governance, and robust protection of your studies and data** across all programs and geographies.

Follow the Series – And Talk to Us

We will publish these insights over the coming months and are happy to discuss how they apply to your current or upcoming studies.

If you'd like to:

- Understand how our evolving QMS can support your protocol's specific risk profile
- Align your own information security expectations with our ISO 27001:2022 implementation
- Explore NIS2-related implications for your European studies and supply chain

please contact us. As Accelsiors' Chief Risk Officer, I will be pleased to connect you with the right experts on our team.

Together, we can turn regulatory evolution into an advantage for your clinical development programs.

Dr Mihaly Juhasz, CEO

Turn Compliance into a Competitive Advantage for Your Trials

We're currently working with sponsors to:

- Reassess study risk profiles under ICH E6(R3)
- Benchmark data protection practices against ISO 27001:2022
- Prepare for NIS2driven cybersecurity and continuity requirements

To explore what this means for your pipeline, contact Istvan Horvath, *Vice-President - Corporate Legal Affairs and Intellectual Property*, at I.horvath@accelsiors.com or visit www.accelsiors.com to arrange a short consultation.

Three Pillars. One Framework



Integrated Compliance Framework
for Sponsor Confidence

At a Glance: What Our Compliance Framework Delivers for You

ICH E6 (R3) – Clinical Quality

- Risk based, proportional oversight focused on patient safety and critical data
- Stronger data integrity controls across decentralized and digital trials
- Clearer expectations and oversight of vendors and technology partners

ISO 27001:2022 – Information Security

- Structured protection of confidential sponsor and patient data
- Controlled access and robust asset management across systems and sites
- Security aware culture backed by continuous training

NIS2 – Cyber & Operational Resilience

- Improved detection and reporting of cyber incidents
- Stronger security across the supply chain
- Business continuity measures to reduce trial disruption

The Clinical Pulse - Industry News

The Accelsiors Clinical Pulse: Reader's Digest

The Bridge: From Gene Editing to Living Drugs

Earlier, we looked at how the discovery of CRISPR by Francisco Mojica and its engineering by Doudna, Charpentier, and Zhang gave us the ability to "edit" the code of life. Today, that ability has evolved into "Living Drugs." We are moving beyond just editing cells in a lab dish (*ex vivo*) to engineering them directly inside the patient's body (*in vivo*). This shift promises to solve the scalability issues of current therapies and bring these cures to millions more patients.

Here is what the industry is reading this week about this next frontier:

1. The "Off-the-Shelf" Revolution: In Vivo CAR-T Therapy

Source: *Nature Reviews Drug Discovery* (September 2025)
& *Nature Reviews Immunology* (October 2025)

The Gist: Current CAR-T therapies require extracting a patient's T-cells, engineering them in a lab, and re-infusing them (a slow, expensive process). This review highlights the shift to **In Vivo CAR-T**, where we inject a vector (like a viral particle or lipid nanoparticle) directly into the patient to engineer their T-cells inside their body.

Why it Matters: This cuts out the complex logistics of "vein-to-vein" manufacturing. Clinical trials are already underway for B-cell malignancies, showing that we can achieve efficient transduction and sustained CAR expression without the wait.

2. Cutting the Cost: Non-Viral Vectors

Source: *Nature Reviews Methods Primers* (October 2024)

The Gist: While viral vectors (lentivirus/retrovirus) are the gold standard, they are costly and hard to manufacture at scale. This paper explores **Non-Viral Vectors** like mRNA encapsulated in Lipid Nanoparticles (LNPs), the same tech used in COVID vaccines.

Why it Matters: Non-viral methods are safer (no risk of accidental genomic integration) and much cheaper to produce. They allow for "transient" expression, meaning we can dose a patient multiple times to control toxicity, a flexibility impossible with permanent viral modifications.



3. The Solid Tumor Challenge: A Clinical Perspective

Source: *Nature Reviews Clinical Oncology* (December 2025)

The Gist: CAR-T has cured blood cancers but struggled against solid tumors. This review argues that the solution isn't just better biology, but better **clinical strategy**. It proposes "Early Apheresis" (collecting T-cells before they are exhausted by chemo) and "Locoregional Delivery" (injecting cells directly into the tumor/organ) to bypass systemic toxicity.

Why it Matters: It shifts the focus from "finding a magic molecule" to "optimizing the clinical trial design", exactly where a Clinical CRO like Accelsiors adds value.

4. The Autoimmune Pivot: From Cancer to Cures

Source: *Nature Reviews Drug Discovery* (September 2025) & *Nature Reviews Immunology* (October 2025)

The Gist: CAR-T therapy was born in oncology, but its most exciting new frontier might be autoimmune disease. Recent studies highlight how CAR-T cells targeting CD19 can achieve an "immune reset," effectively wiping out the autoreactive B-cells responsible for diseases like Systemic Lupus Erythematosus (SLE), Multiple Sclerosis (MS), and Myositis.

Why it Matters: Unlike lifelong immunosuppressive drugs that only manage symptoms, this approach mimics a "factory reset" for the immune system. Early clinical data suggests patients can achieve durable, drug-free remission.



5. The "Safety Switch": Logic-Gated CARs

Source: *Nature Reviews Clinical Oncology* (December 2025)

The Gist: One of the biggest risks in treating solid tumors is "on-target, off-tumor" toxicity, where CAR-T cells attack healthy tissue that happens to express the same antigen as the cancer. To solve this, scientists are developing "Logic-Gated" CARs. For example, the EVEREST-2 trial is testing a CAR that activates only if it sees the tumor antigen (Mesothelin) AND recognizes that the cell has lost a specific healthy marker (HLA-A*02).

Why it Matters: This biological circuitry allows for surgical precision at a cellular level. It effectively creates a safety switch that protects vital organs, allowing us to target aggressive solid tumors that were previously considered "undruggable" due to safety risks.

From the Lab Bench to the Bedside: The Great Translation

You have spent years mastering the pipette. You know the exact pH of your buffer, and you have stayed up until 3 AM waiting for a centrifuge to finish.

But now, you are stepping into the world of Clinical Research. Suddenly, nobody is asking about your "novel mechanism." They are asking about "Data Integrity," "TMFs," and "ICH-GCP."

It can feel like landing on a different planet. But here is the secret: **You aren't leaving science behind. You are just learning a new language.**

The Culture Shift: Novelty vs. Reliability

In Academia, the currency is Discovery. You are rewarded for finding something new. A novel pathway, a surprising result.

In Clinical Research (CROs), the currency is Reliability. We are rewarded for proving that a treatment is safe, effective, and reproducible for millions of people.

The "Translator" Guide: How Your Skills Transfer

Don't hide your academic background. Use it. Here is how to translate your "Lab Skills" into "Industry Superpowers":

The Academic Skill	The Clinical Research Superpower
<p>Troubleshooting a failed experiment: You systematically checked every variable to find the error.</p>	<p>Root Cause Analysis (CAPA): When a clinical site has a protocol deviation, you are the detective who finds why it happened and how to stop it from happening again.</p>
<p>Writing Grant Proposals: You had to convince a committee your idea was worth funding.</p>	<p>Protocol Design & Feasibility: You know how to build a scientific argument that convinces regulators (FDA/EMA) that a trial is safe and necessary.</p>
<p>Managing Lab Notebooks: You meticulously recorded every step so others could reproduce it.</p>	<p>Good Documentation Practice (ALCOA+): In our world, "if it isn't documented, it didn't happen." Your obsession with detail is your greatest asset.</p>

The "Mindset Check"

Scenario: You receive data from a patient in a trial showing a sudden, unexpected spike in liver enzymes.

- **The Academic Mindset:** "Wow, that's fascinating! Is this a new biological phenotype? Let's design a side-experiment to explore the mechanism."
- **The Industry Mindset:** "Stop. Is this a Safety Signal (SUSAR)? We need to verify the data, notify the Medical Monitor immediately, and ensure patient safety."

The Lesson: In the lab, an anomaly is an opportunity. In the clinic, an anomaly is a risk. The best professionals are those who can spot the anomaly with their scientific eye, but manage it with their clinical discipline.

Your Future at Accelsiors

Are you ready to translate your curiosity into a cure? We are looking for "Bilingual" professionals who speak both Science and Safety. [Send us your bio!](#)

The Patient Voice

From "Patient" Back to "Person": The Promise of Next-Gen CAR-T

For anyone battling a chronic disease, the hospital eventually becomes a second home. A place of treatment, but also of isolation.

The promise of the next-generation CAR-T therapies we discussed in this week's Reader's Digest isn't just about higher efficacy rates in a spreadsheet. It is about **liberation**.

The Burden of "Standard of Care" Traditional treatments often mean an endless cycle of chemotherapy infusions, weekly clinic visits, and the constant physical toll of toxicity. Even early CAR-T therapies required weeks of mandatory inpatient monitoring due to risks like Cytokine Release Syndrome (CRS), keeping patients separated from their families during their most vulnerable moments.

The "Living Drug" Revolution: The new wave of In Vivo and mRNA-based CAR therapies offers a glimpse of a different future:

- **Outpatient Potential:** Because mRNA vectors are transient and carry a lower risk of long-term toxicity, we are moving toward a world where gene therapy could be as simple as an outpatient infusion. Patients get their treatment and go home to sleep in their own beds.
- **Treatment-Free Remission:** As a "Living Drug," these cells can persist and protect the patient for years, potentially replacing daily pills and weekly drips with a single "one-and-done" treatment.

Accelsiors' Commitment

At Accelsiors, we design clinical trials with this reality in mind. We don't just measure if the drug works; we measure if the treatment works for the person. By advocating for **Patient-Reported Outcomes (PROs)** and **Decentralized Trial elements** (like home nursing visits), we ensure that the path to a cure doesn't come at the cost of the patient's life.



How do you build "Patient Centricity" into a rigorous Phase I/II Protocol?

Moving from "patient-centric concepts" to an approved protocol requires a shift in design. Here is how Accelsiors helps sponsors implement these strategies while satisfying regulatory authorities (FDA/EMA):

1. The "Hybrid" Safety Protocol (Outpatient Readiness)

The Challenge: Regulators are wary of outpatient CAR-T due to the risk of sudden CRS/ICANS.

The Implementation: We design a "Safe Haven" protocol.

- **Remote Monitoring:** Patients wear medical-grade biometrics (like continuous temperature/O2 patches) that feed real-time data to the site.
- **The "2-Hour Rule":** Instead of keeping patients in the hospital for 14 days, the protocol mandates they stay in a hotel or apartment within a 2-hour radius of the site.
- **Result:** The patient sleeps in a comfortable bed with family, but safety is compromised.

2. Digitizing the Patient Experience (ePROs)

The Challenge: Patients forget how they felt 3 weeks ago. Paper diaries have low compliance.

The Implementation: We integrate BYOD (Bring Your Own Device) ePROs.

- **Triggered Alerts:** Instead of a generic daily survey, the app triggers specific questions based on the patient's biometrics (e.g., "Your temperature is slightly elevated. Do you feel chills?").
- **Validated Instruments:** We utilize FDA-recognized scales like **PROMIS** (Patient-Reported Outcomes Measurement Information System) or **FACT-G** to ensure the data supports future labeling claims.

3. The "Rapid Initiation" Design

The Challenge: "Vein-to-vein" time is often the biggest barrier to recruitment and retention.

The Implementation: We write protocols that allow for "Parallel Screening."

- While the patient is finishing their bridging therapy, we are already clearing their eligibility for the trial.
- For "Off-the-Shelf" (Allogeneic) or "In Vivo" trials, we aim for a "7-Day Screen-to-Needle" timeline, minimizing the anxiety of the waiting game.



The Challenge: The "Vein-to-Vein" Race Against Time

The Scenario: You are running a Phase I CAR-T trial for patients with advanced Gastric Cancer. The current protocol requires patients to fail two lines of chemotherapy before they undergo apheresis (T-cell collection).

The Problem: Manufacturing your CAR-T product takes 28 days. By the time the cells are ready, 30% of your enrolled patients have experienced rapid disease progression and are no longer eligible for infusion. The trial is stalling.

What is the most effective clinical strategy to save this trial?

- A. **Increase the dosage** of the bridging chemotherapy to keep the disease stable for longer.
- B. **Switch to "Early Apheresis"**—amend the protocol to collect T-cells *before* the patient starts second-line treatment, banking them for later use.
- C. **Broaden the eligibility criteria** to allow sicker patients to receive the infusion regardless of progression.

Scroll to reveal
the answer



According to recent clinical data (such as the CT041-CG4006 trial), patients with aggressive solid tumors often deteriorate faster than the manufacturing timeline allows.

Moving apheresis earlier, collecting cells before the patient is exhausted by multiple lines of chemo, solves two problems:

1. **It secures the product:** You have the cells ready on the shelf before the patient relapses, cutting the "wait time" to near zero when they need it.
2. **It improves "Fitness":** T-cells collected earlier are less "exhausted" (more stem-like memory phenotype), leading to better expansion and durability in the patient.

The Answer is B: Switch to Early Apheresis

Deep Dive: This is just one of 5 critical strategies on treating Multiple Sclerosis. [Download our White Paper: CAR T-Cell Therapy: A Paradigm Shift for Autoimmune Disease with a Focus on Multiple Sclerosis](#)

The 2026 Clinical Crystal Ball: What 2025 Taught Us About the Future

As the year draws to a close, it is tempting to look back at the milestones we have passed. But at Accelsiors, our focus is always on the road ahead.

We have spent 2025 analyzing the shifting landscape of clinical research, from the breakthroughs in **In Vivo engineering** to the massive regulatory overhaul of **ICH E6(R3)**. Based on the data, we believe 2026 will not just be "business as usual." It will be the year when three major trends move from "experimental" to "essential." Here is what we predict will define your clinical strategy next year:

Trend 1: The "Living Drug" Goes Outpatient



- **The Shift:** For a decade, cell therapy has been synonymous with complex logistics and prolonged hospitalization. But as we saw in this year's Nature Reviews breakthroughs, the rise of mRNA and **In Vivo CAR-T** is changing the safety equation.
- **The 2026 Prediction:** We expect to see the first wave of "**Hybrid Safety Protocols**" for gene therapy. Sponsors will push for outpatient administration supported by rigorous remote monitoring. The challenge will shift from "managing logistics" (vein-to-vein) to "managing data" (real-time home monitoring).
- **Accelsiors' Take:** We are already designing protocols that utilize medical-grade wearables to ensure patient safety without the hospital confinement.

Trend 2: Quality by Design (QbD) Becomes the New Standard



- **The Shift:** The finalization of **ICH E6(R3)** marks a paradigm shift. It moves Good Clinical Practice (GCP) from a "checkbox" exercise to a **Quality by Design (QbD)** approach. With the guideline taking effect in late 2025, the industry is facing its biggest compliance overhaul in decades.
- **The 2026 Prediction:** 2026 will be the year of "Compliance Shock." Many organizations will struggle to operationalize these new principles, realizing too late that their old SOPs are no longer sufficient for the risk-based approach R3 demands.
- **Accelsiors' Take:** We are ready. While others are still reading the guidance, we have already implemented QbD principles into our Quality Management System. We don't just "check" quality at the end; we design it into the protocol from day one.

Trend 3: Patient Centricity Becomes a Regulatory Mandate



- **The Shift:** "Patient Centricity" used to be a buzzword. Now, with new FDA and EMA guidance on diversity and trial accessibility, it is a compliance requirement.
- **The 2026 Prediction:** Protocols that do not offer **Decentralized Clinical Trial (DCT)** elements, like home nursing visits, ePROs (electronic Patient-Reported Outcomes), or reimbursement for travel, will struggle to gain regulatory approval and will fail to recruit. The "burden of participation" will become a key metric in protocol feasibility.
- **Accelsiors' Take:** We view the patient's convenience as a critical data quality assurance measure. A supported patient is a compliant patient, and that leads to cleaner data.

Our Promise for the New Year

The tools of our trade are changing, but our mission remains the same. Whether it is navigating the new regulatory landscape of ICH E6(R3) or designing a patient-friendly hybrid trial, Accelsiors is ready to be your partner in 2026.

**From all of us at Accelsiors,
we wish you a restful holiday season
and a breakthrough year ahead**