Clinical Excellence
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15 Red Flags That Derail Clinical Trials with Advanced Therapies Before First Patient In

Avoid costly delays, audit findings, and operational chaos before your clinical trial even begins.

I. Introduction

Working on clinical trials with advanced therapy medicinal products (ATMPs) requires more than just scientific rigor. It demands a holistic approach that integrates meticulous planning, cross-functional communication, and a keen awareness of the unique hurdles these therapies present. Because these treatments are often tailored to individual patients or small populations, logistical challenges and regulatory expectations can quickly become overwhelming if not addressed early.

Sponsors and investigators must navigate a landscape filled with strict regulatory requirements, complex manufacturing needs, and the necessity for specialized handling and storage of advanced therapy products. Furthermore, ethical considerations, such as patient consent and long-term monitoring, add another layer of responsibility.

The foundation you set before enrolling your first patient is critical; it shapes not only the efficiency of your clinical trial, but also its compliance, safety outcomes, and credibility in the eyes of regulators and stakeholders.

By embracing a proactive mindset and leveraging comprehensive checklists and tools, your team can transform potential setbacks into opportunities for excellence, ensuring that the promise of cell and gene therapies moves steadily from concept to patient benefit.

Let's dive in and ensure your clinical trial is set up for success!

What is in it for you?

1. Enhanced Compliance: By following the checklist, you can ensure that all regulatory guidelines are met, reducing the risk of non-compliance and potential audit issues.
2. Improved Efficiency: The checklist helps streamline processes and procedures, minimizing delays and operational problems that can arise during clinical trials.
3. Risk Mitigation: Identifying and addressing common pitfalls early on helps mitigate risks associated with product complexity, team readiness, and oversight, leading to a smoother clinical trial process.
4. Better Team Coordination: The checklist promotes clear communication and alignment among team members and vendors, ensuring everyone is on the same page and working towards the same goals.

The Author

Jessica Cordes studied Molecular Life Science in Luebeck and started her business career for 2 years at the Central Lab MDS Pharma Services as a project manager.

She moved to GlaxoSmithKline in 2009 where she worked as country project leader for 4 years.

In 2013, she started at MorphoSys, working in an international role as a clinical trial leader overseeing clinical trials with antibodies and starting with line management responsibilities.

She then moved in 2017 to Medigene as clinical trial manager, planning and implementing a cell therapy clinical trial, where she took over the leadership for Clinical Operations in 2018 while building the group.

In 2021, she joined Immatics being responsible for building a global cohesive Clinical Operations department and leading the operational strategy for the global conduct of all clinical trials.

Since 2023, she has been working as a Senior Consultant and Trainer in her own company Clinical Excellence. She supports small companies in setting up and developing their internal clinical development organization by structuring the department and defining GCP processes as well as providing training. She also supports them in planning and implementing their clinical trials.

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RED FLAGS with 🧠 Strategy & Planning

1. No formal gap assessment against current EMA/FDA ATMP guidelines.
   → You're starting blind and have the risk missing fundamental compliance issues.
2. Clinical Operations leadership is unclear or overloaded.
   → Clinical trial oversight is treated as a side job instead of a dedicated, strategic function.
3. FIH readiness is based on assumptions, not evidence.
   → No structured readiness checklist, inspection simulation, or internal risk review.

RED FLAGS with 📄 SOPs & Systems

4. Missing or outdated SOPs specific to advanced therapies.
   → Generic SOPs don't account for unique ATMP requirements (e.g., chain of custody, temperature excursions).
5. No version-controlled document management system in place.
   → Teams can't reliably access or track essential clinical trial documents.
6. Training is ad hoc or based solely on generic GCP modules.
   → No clinical trial- or product-specific training lead to compliance and performance risk.

RED FLAGS with 🧪 Product & Protocol Complexity

7. Protocol complexity is misaligned with site capabilities.
   → Sites may accept the clinical trial but won't be able to execute it well.
8. No clear plan for managing logistics of manufacturing, shipment, and handling.
   → Breakdowns in product flow can halt the entire clinical trial before it begins.
9. No quality risk management plan tailored to ATMP clinical trials.
   → No proactive identification of high-risk process points can cause reactive firefighting.

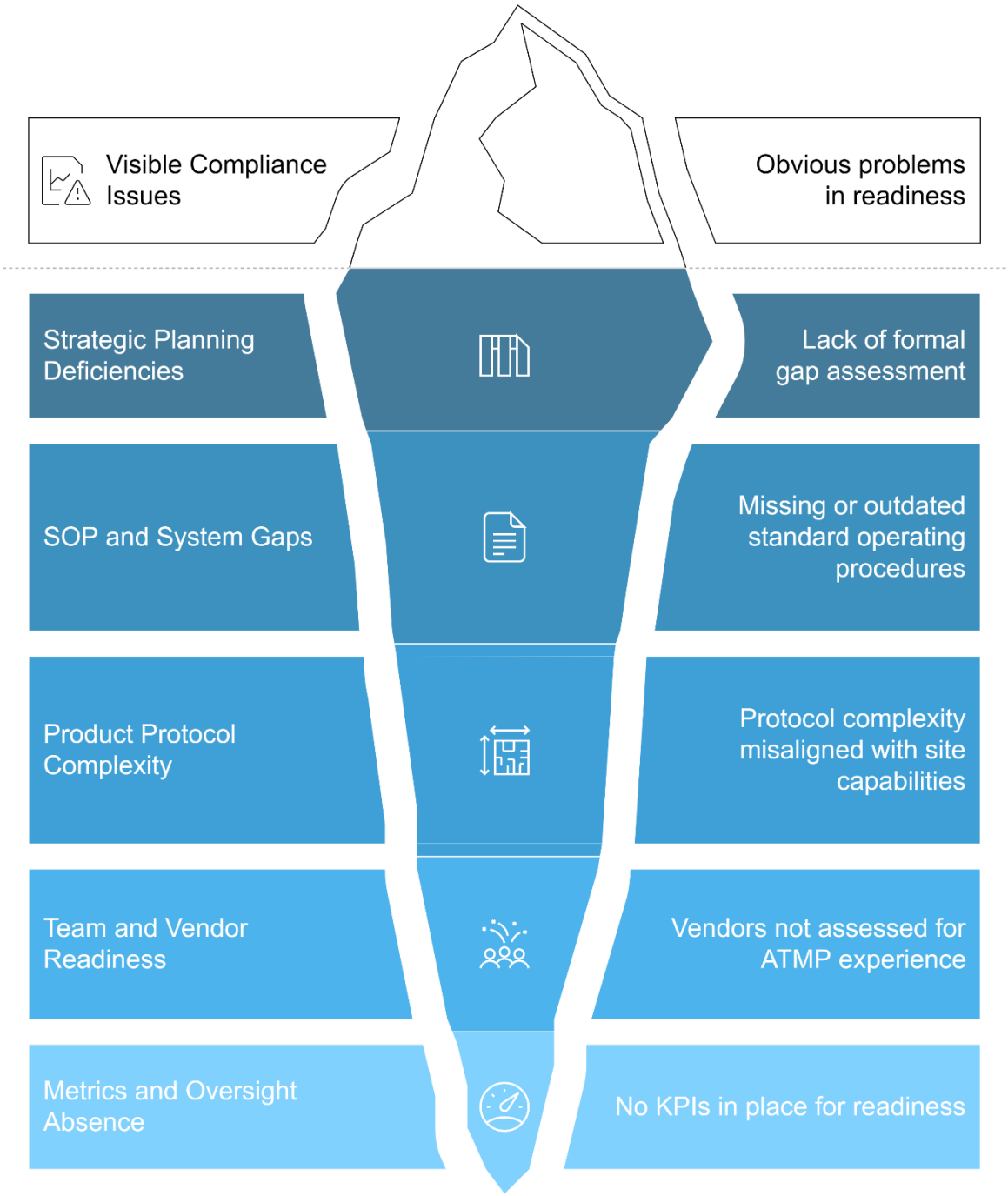
RED FLAGS with 👥 Team & Vendor Readiness

10. Vendors (CROs, labs, couriers) aren't assessed for ATMP clinical trial experience.
    → You risk relying on partners who don't understand the stakes or complexity.
11. Lack of onboarding plan for internal staff or external partners.
    → Everyone's learning on the job at the cost of time, quality, and credibility.
12. No cross-functional launch meeting or communication plan.
    → Silos between CMC, Clinical, and Regulatory creates misalignment from day one.

RED FLAGS with 📈 Metrics & Oversight

13. No KPIs in place for FPI readiness.
    → You don't know what success looks like or when you're off track.
14. No inspection preparedness strategy (e.g., mock audits, TMF spot checks).
    → First-patient-in could be the first real test and that's a risk.
15. Audit or CAPA history not reviewed to inform new clinical trial setup.
    → Repeating the same mistakes from previous programs or clinical trials because "you have always done it this way."

ATMP Clinical Trial Readiness: Unveiling Hidden Risks



Want to see how your Clinical Trial Set-up compares?

Book a 20-minute consult

and walk through your Red Flags

— together with me.

Book a Meeting

If you are interested in getting a deeper understanding of the risk-based approach mandated by the updated Good Clinical Practice Guideline ICH E6(R3), and want to put it into the context of ATMP clinical trials, please enroll in my digital training course:

Good Clinical Practice for ATMPs - Refresher

Enroll via the Clinical Excellence Training Academy