

Clinical Excellence: From Framework to Findings

Validating MSC Efficacy in SLE/CKD
through GCP 3rd Edition Standards



The Blueprint

GCP 3rd Edition

Establishing global standards for risk management, electronic records, and patient safety.

The Builders

Clinical Ecosystem

The balance of accountability across Sponsors, Investigators, and Regulators.

The Building

MSC Clinical Data

Unpacking the 4-year and 1-year clinical trial outcomes for Mesenchymal Stem Cell treatments in SLE/CKD.

Key Takeaway: Rigorous regulatory compliance is the foundation that makes breakthrough clinical data precise, credible, and safe.

The Uncompromising Purpose of GCP

Subject Protection

Prioritizing patient rights and safety above all else. Validated through rigorous Informed Consent processes approved by the IRB.

Scientific Validity

Protocols designed based on the latest scientific knowledge and rigorous feasibility assessments.

Data Integrity

Delivering clinical data that is highly credible, precise, and consistent.

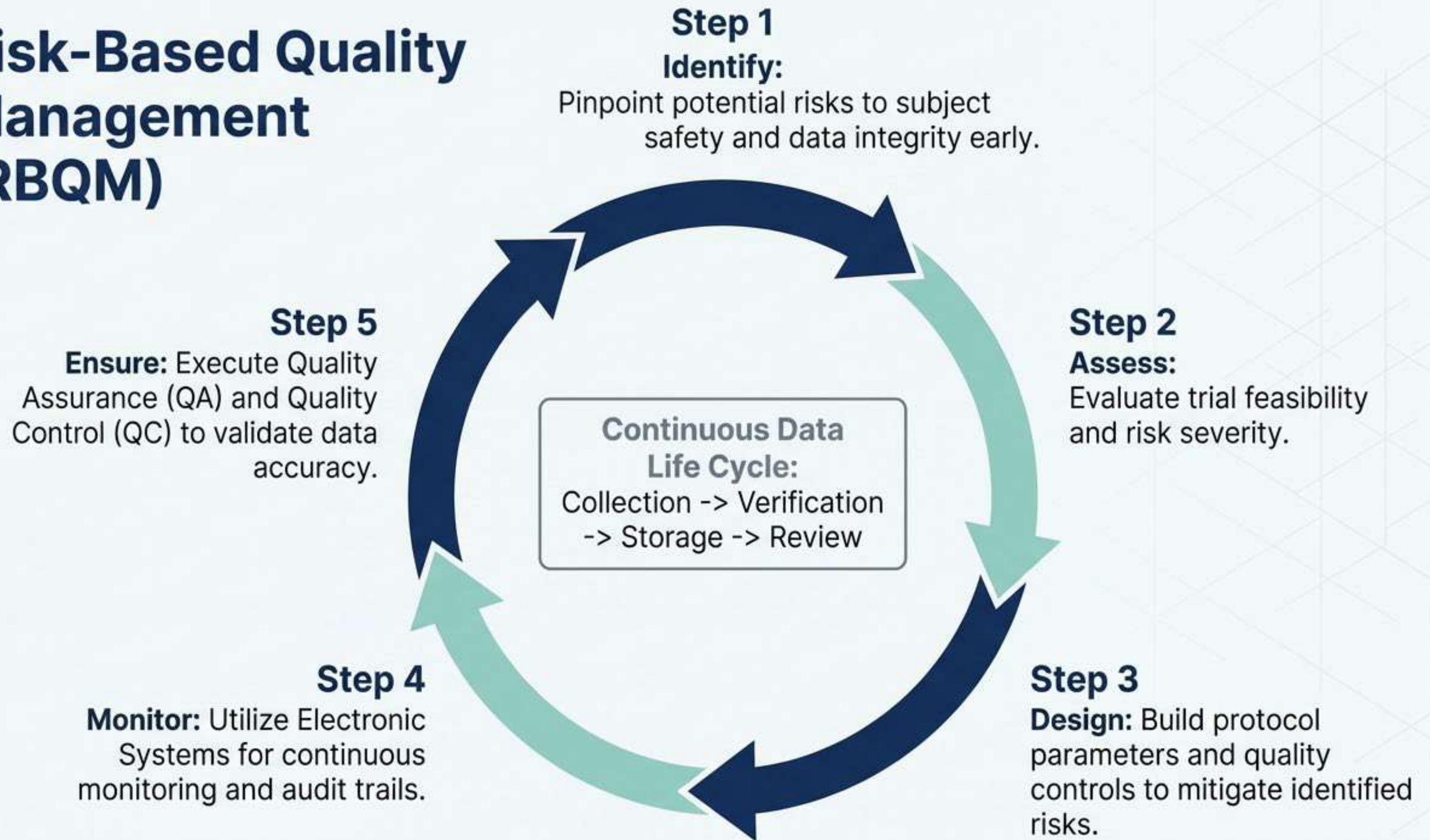
Declaration of Helsinki

The ethical bedrock of all human trials

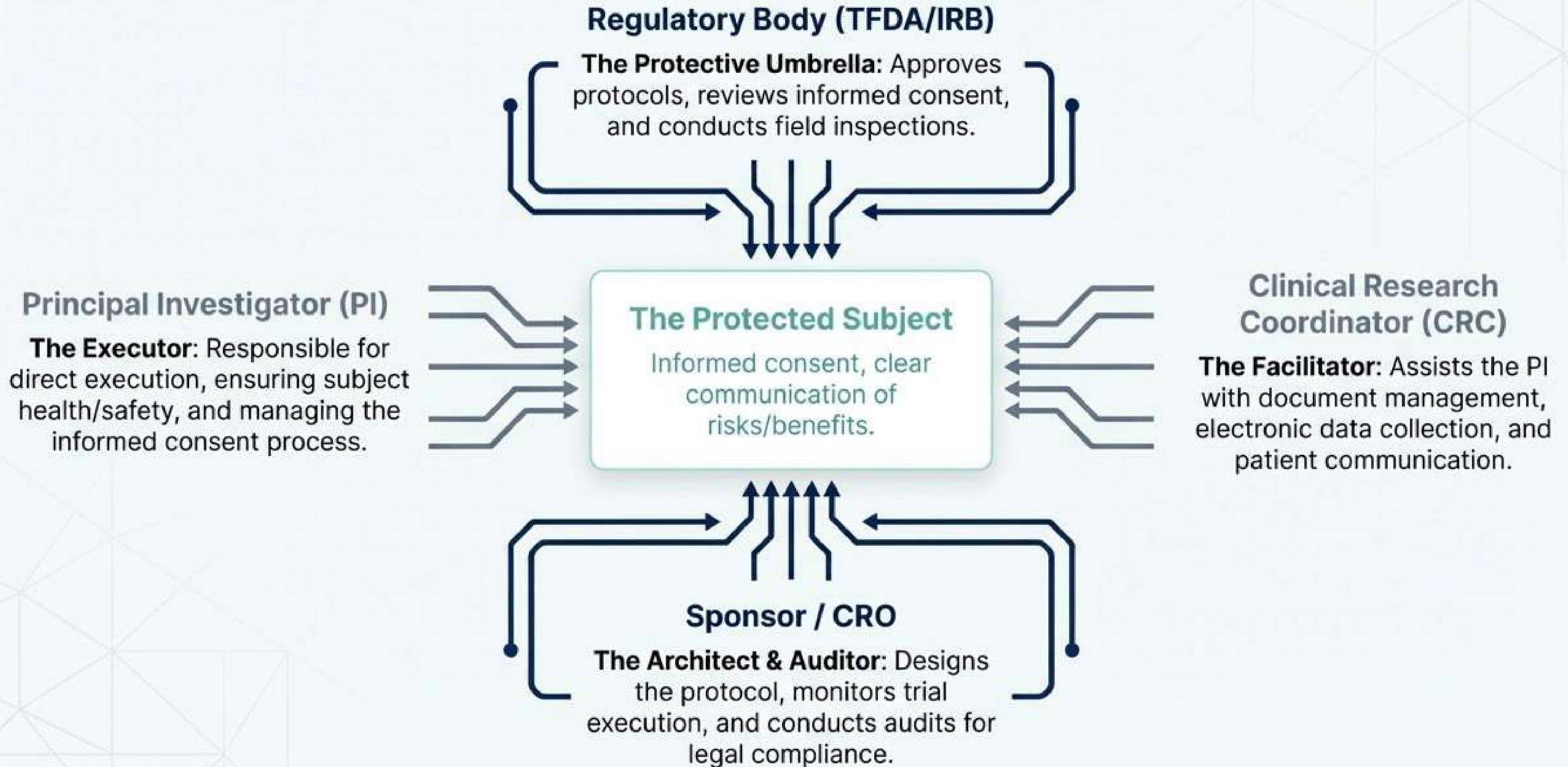
The GCP v3 Shift: From Reactive to Proactive

	Older GCP Methods		GCP 3rd Edition
Data Capture	Manual, paper-based records	➤	Electronic Systems (EDC) with automated tracking
Audit Trails	Reactive discovery	➤	Immutable electronic logs showing every modification and access point
Quality Strategy	Retrospective correction	➤	Proactive Risk-Based Quality Management (RBQM) embedded in protocol design
Data Validation	Labor-intensive paper review	➤	Continuous electronic data collection, verification, and review life cycles

Risk-Based Quality Management (RBQM)



The Clinical Accountability Ecosystem





The Value of the Framework

Rigorous GCP compliance ensures that breakthrough clinical data is precise, credible, and safe.

The following MSC trial results are not just observed—they are scientifically validated under strict operational scrutiny.

Clinical Efficacy: MSC Treatment for SLE/CKD

Study 1: 87 Patients

Study 2: 81 Patients



Target Pathology: Lupus Nephritis (SLE/CKD)

The Baseline Protocol

Two major clinical studies observing the safety and efficacy of Mesenchymal Stem Cell (MSC) intervention.

Critical Protocol Variable:

In the 87-patient study, the protocol explicitly excluded the use of steroids or immunosuppressants, isolating the pure efficacy of the MSC treatment.

Study 1: The 4-Year Recovery Trajectory

Cohort Data: 87 Patients | 4-Year Follow-Up

Month 6
Rapid Response
Proteinuria drops sharply by **-45%**

Year 1-3

System Improvement

GFR Improves: **+23%**
Albumin Increases: **+13%**
Complement C3 Increases: **+36%**

Disease activity demonstrably lowered.

Year 4

Long-Term Outcome

Complete Remission Rate: **50%**
Total Relapse Rate: **23%**

Study 2: Independent 1-Year Confirmation (China)

Cohort Data: 81 Patients | 1-Year Follow-Up

Proteinuria Reduction

-48%

reduction in urinary protein at 12 months.

Renal Markers

- **+19%** GFR Improvement
- **+18%** Albumin Increase
- **+36%** Complement C3 Increase

Remission Rates

60.5% Partial Remission

30.9% Complete Remission

within just 12 months.

Relapse

22.4%

overall relapse rate.

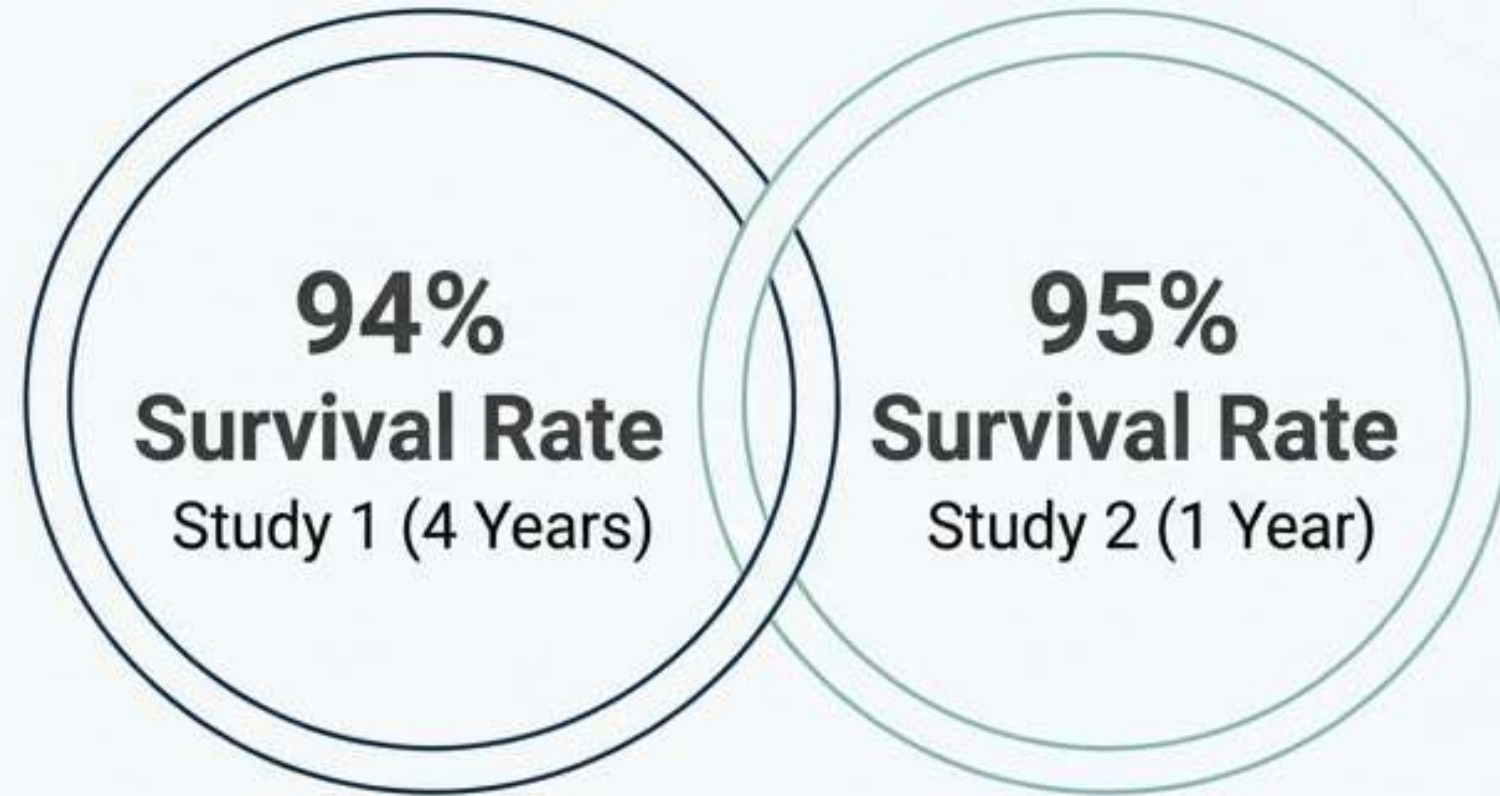
MSC Trial Concordance: Study 1 vs. Study 2

Metric	Study 1	Study 2
Cohort Size	87 Patients	81 Patients
Follow-Up	4 Years	1 Year
Proteinuria Reduction	-45% (at 6 mo)	-48%
GFR Improvement	+23%	+19%
Complement C3 Increase	+36%	+36%
Relapse Rate	23%	22.4%



Remarkable statistical consistency across independent cohorts validates the mechanism of action.

Validating the Safety Profile



The Mortality Clarification

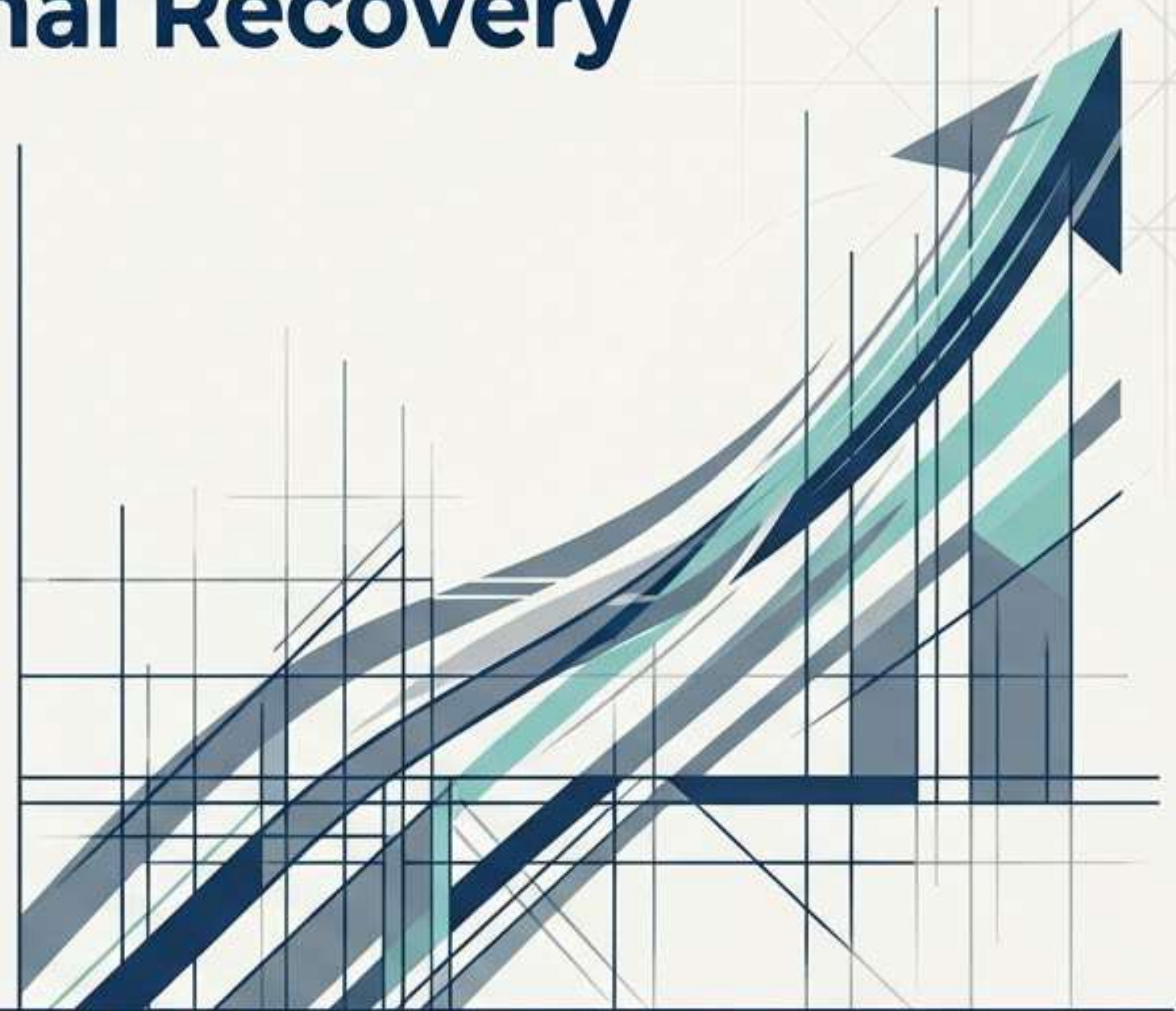
Study 1 recorded 5 deaths (6%).
Study 2 recorded 4 deaths (5%).

Rigorous GCP audit and clinical review confirmed that 100% of these mortalities were strictly unrelated to the MSC injections.

Takeaway: The intervention proves biologically potent while maintaining exceptional clinical safety.

Conclusion: Validated Renal Recovery

- ✓ **Reduced Inflammation:** MSCs demonstrably lower disease activity and systemic inflammation in Lupus Nephritis.
- ✓ **Restored Function:** Consistent, durable improvements in Glomerular Filtration Rate (GFR) and Proteinuria reduction.
- ✓ **Proven Safety:** High survival rates with no mortality linked to the MSC intervention.



Breakthrough efficacy for SLE/CKD, captured and verified through the uncompromising standards of GCP 3rd Edition.