



Why Wait for Real Data?

The Power of Synthetic Data in Modern Clinical Trials

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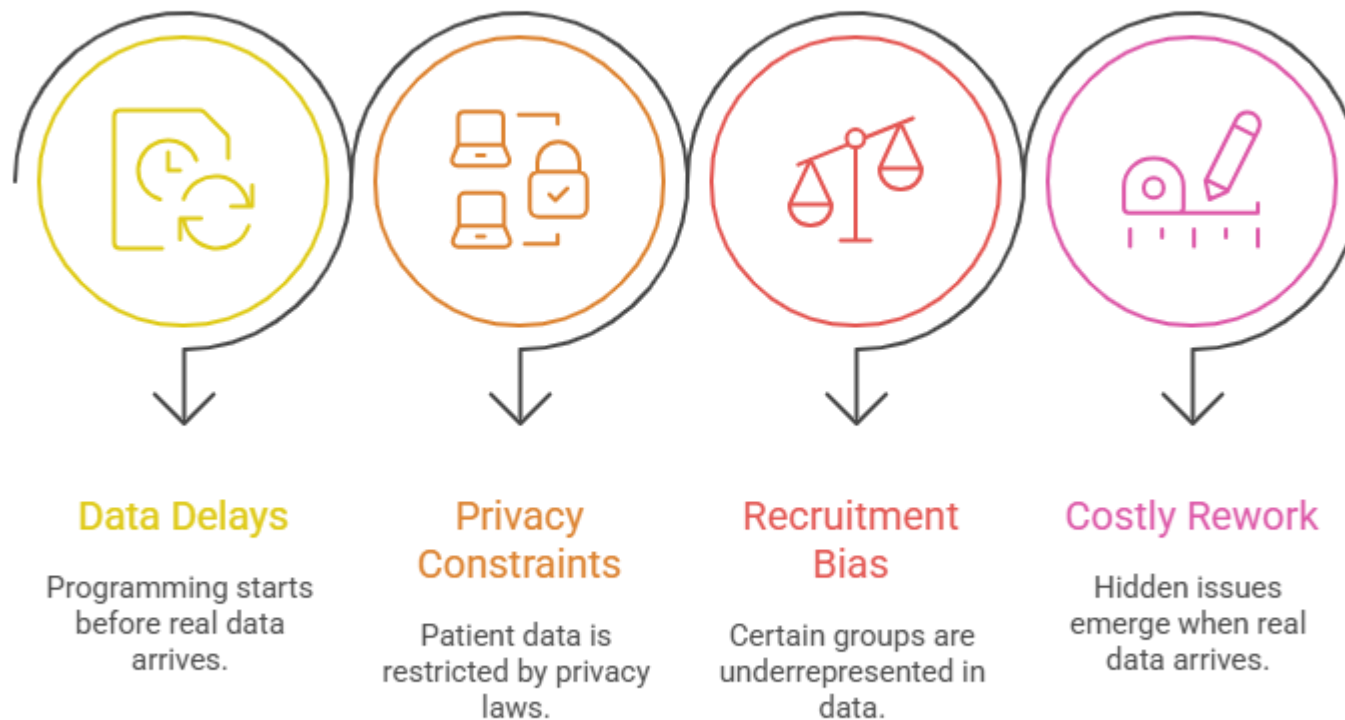
Agenda

- Challenges
- Why Synthetic Data?
- What is Synthetic Data?
- How Synthetic Data Is Generated
- Governance & Trust
- Applications in Clinical Trials
- Conceptual Workflow
- Benefits & Impact
- Future Outlook



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The Problem in Modern Trials



Why Synthetic Data?



Empower AI & Automation

Train and test models on realistic data.



Support Diverse Datasets

Simulate under-represented demographics.



Reduce Costly Rework

Detect errors early in mock runs.



Enable Early Development

Start building pipelines before real data arrives.



Accelerate Time-to-Insight

Front-load validation and QC processes.



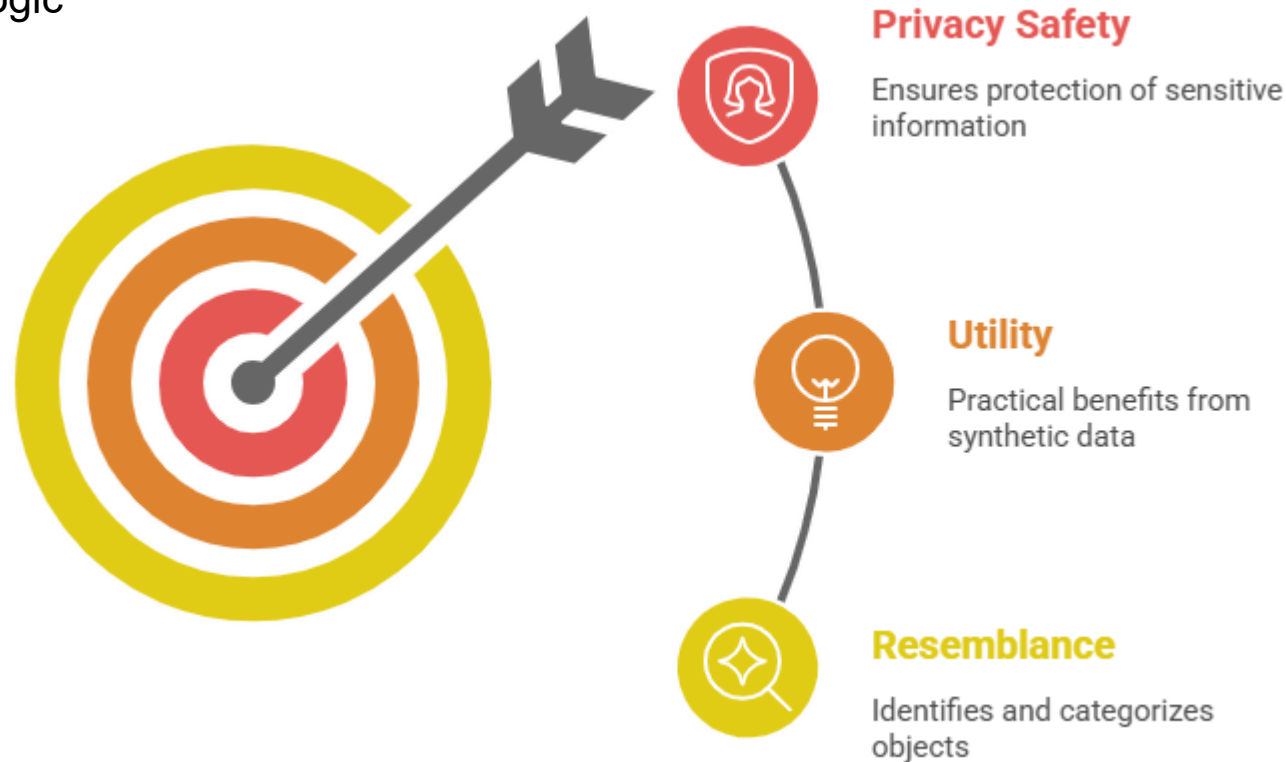
Preserve Patient Privacy

Work in a safe sandbox environment.



What Is Synthetic Data (Definition & Goals)

- Artificially generated; no real patient records
- Mirrors relationships, timing, logic



How Synthetic Data Is Generated

1. Rule-based simulation
2. Machine-learning (GANs/VAEs)
3. Hybrid/constraint-based
4. Perturbed semi-synthetic



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Governance & Trust

- Transparent generation methods.
- Validation metrics (KS test, utility score, privacy risk).
- Audit trails & versioning.

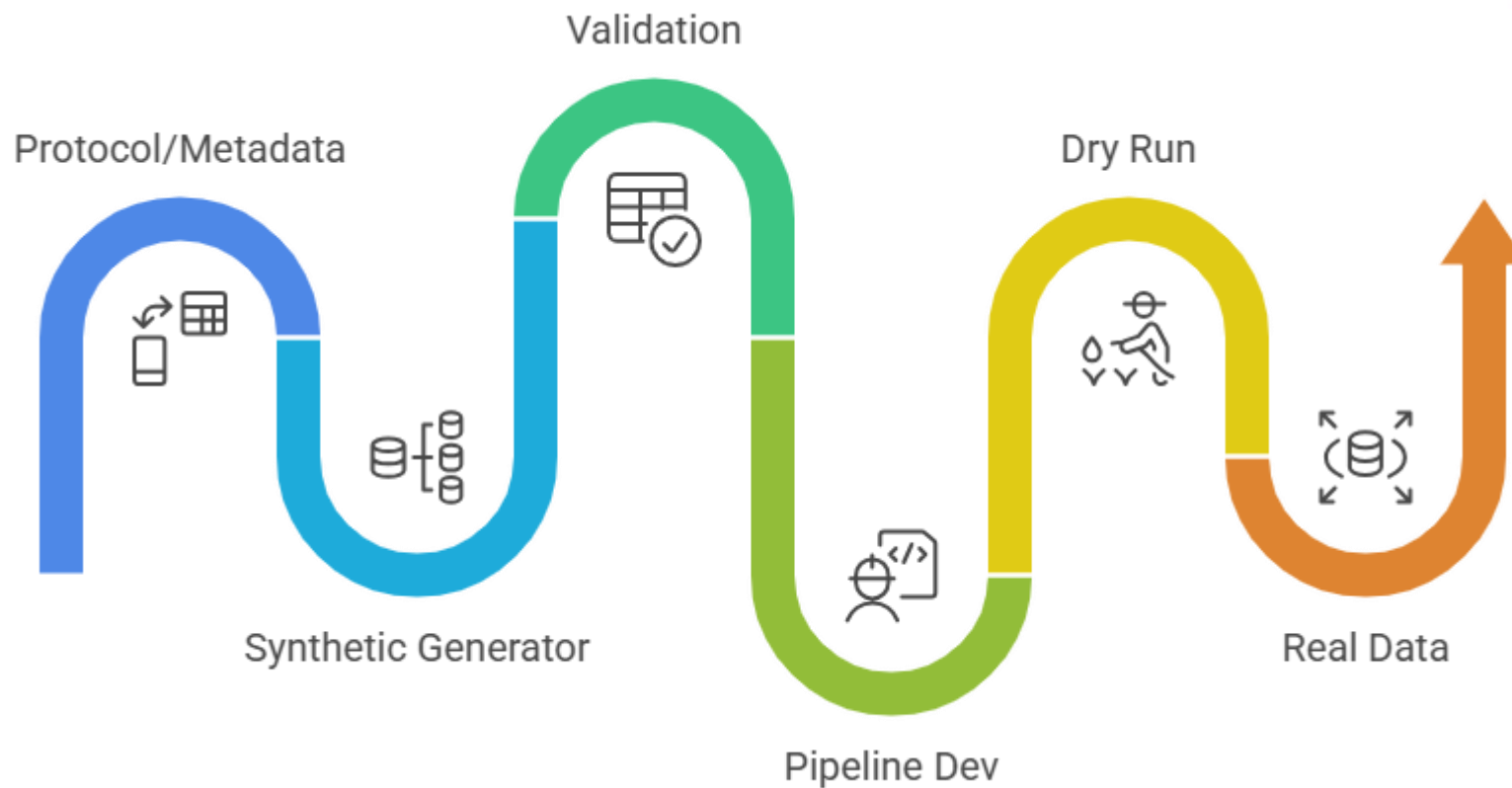


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Applications in Clinical Trials

Function	Example Use	Outcome
Data Mgmt	Edit-check testing	Early error discovery
Programming	SDTM/ADaM mockups	Faster builds
Biostats	TFL dry runs	Reduced rework
AI/ML	Model training	Bias testing & scalability

Conceptual Workflow



Benefits & Impact

- Time-to-deliverable acceleration
- Cost efficiency
- Higher quality & robustness
- Privacy-safe sandboxing
- Bias stress-testing
- Continuous iteration



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Future Outlook

- AI & Generative Models → domain-trained, privacy-aware.
- Real-World Data Fusion → hybrid synthetic arms.
- Automation & Human-in-the-Loop QC → CI/CD integration.
- Regulatory modernization → guidance evolving.



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