

TrialChain™

Consent Management & Data Access Audit Trail for Clinical Trials

THE PROBLEM

- No consent version control
- Manual audit trails (compliance risk)
- FDA warnings (500+/year)
- GDPR fines (\$4.5M+ per breach)
- Offline sites = sync hell

THE SOLUTION

- ✓ Tokenized consent versioning
- ✓ Immutable access audit trail
- ✓ Auto-compliance (FDA/HIPAA/GDPR)
- ✓ Revocation + re-consent workflows
- ✓ Offline-first (DUAL-powered)

MARKET OPPORTUNITY

Clinical Trial Mgmt: \$7B
Consent/Compliance: \$2B TAM
CRO Market: 7.2% CAGR

Buyers:
IQVIA, Parexel, Charles River
+ 5000+ pharma/biotech firms

90-DAY MVP

1 CRO, 1 Trial, 50-200 patients

Deliverables:

- Consent token generation
- Access event logging
- Revocation workflows
- Audit reports
- HIPAA compliance check

REVENUE MODEL

Per-Patient SaaS:
\$5-15 per patient

Monthly Trial SaaS:
\$5K-20K per trial

Y1 Projection: \$400K ARR
Y5 Projection: \$45M+ ARR

\$500K

Pre-Seed
18-month runway

Use of funds:
• Engineering: \$250K
• Product: \$150K