GENBIOCA
Domain Led, Technology Services Company

GBC-DigiPro™

AI-Native Digital Protocol Platform & Lifecycle Management

Structure once. Validate automatically. Propagate everywhere.

Protocol deviations, inconsistent endpoints, and downstream data errors cost clinical sponsors millions and delay trial timelines. Manually keying the same trial design parameters across dozens of clinical systems creates compliance gaps before the study even launches.

GBC-DigiPro transforms protocol design into machine-readable CDISC USDM v4.0 data. From AI-assisted authoring to real-time ICH M11 CeSHarP compliance and instant legacy PDF extraction, DigiPro creates an auditable single source of clinical truth.

Supported Industries & Frameworks

AI Protocol Studio & ICH M11 Compliance

Author study endpoints benchmarked across hundreds of peer protocols. One-click ICH M11 CeSHarP validation highlights blockers and warnings with direct navigation to the exact field needing remediation.

Automated Cross-Reference Engine

Automatically validates interconnected parameters across every protocol section (such as Endpoints to ICF alignment), removing manual checklists

Legacy PDF to USDM Conversion

Extracts legacy protocol libraries at 50 pages per minute into structured CDISC USDM JSON. Features element-level confidence scoring and human-in-the-loop review gates with ALCOA++ attribution.

Single Protocol Downstream Document AutoGen

One approved digital protocol auto-populates first drafts of ICFs, SAPs, DMPs, Monitoring Plans, and TMF indexes in under 10 minutes—passed directly into **ClinWrite** for GxP review.

Simultaneous Multi-Region Packages

Automatically prepares and validates aligned submission packages for the FDA (Dataset-JSON v1.1), EMA (CTIS CTA), and CDSCO (Schedule Y).

EHR Feasibility Analytics

Live queries through Epic FHIR and TriNetX project eligible patient recruitment pools and evaluate investigator site capacity before finalizing design.

The Digital Protocol Impact

Dimension	Legacy Protocol Process	GBC-DigiPro Platform
Protocol Format	Static, unstructured PDF documents.	Machine-readable CDISC USDM v4.0 JSON
ICH M11 Compliance	Manual retrospective checklists	Real-time automated gap & blocker detection
Downstream Setup	Weeks of manual re-keying into 10+ systems	First drafts generated in <10 minutes
Legacy Protocol Utility	Trapped in archive filing cabinets	Converted at 50 pages/minute to live data

Visit **genbioca.com**
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