














App Development Plan









Biometrics

ITEM	STATUS	LOGS
Study Designer		
Dose Escalation Simulator	 35%	Online and Local Apps for Dose Escalation Designs. Upcoming: Perform A+B, Rolling-Six, CCD, TPI, mTPI, mTPI2 / Keyboard, BOIN, TEQR, I3+3 and WW designs.
Proof of Concept Simulator	 12%	Online and Local Apps for Proof of Concept Designs. Upcoming: Perform Simons' Two Stage and Bayesian Continuous Monitor designs.
Group Sequential Calculator	 42%	Online and Local Apps for Group Sequential Designs. Upcoming: Perform 1) equally spaced upper boundary including Pocock, Haybittle-Peto, O'Brein-Fleming, and Wang-Tsiatis; 2) Equally spaced lower boundary including Gould-Pecore, Pampallona-Tsiatis, Emerson-Fleming, Jennison-Turnbull, and Whitehead-Stratton; 3) Flexible boundary with α spending function including Lan-DeMets, Hwang-Shih-DeCani, and Kim-DeMets.
Sample Size Re-estimation Calculator	 26%	Online and Local Apps for Sample Size Re-estimation Designs. Upcoming: Perform 1) conditional probability calculation; 2) Weighted P or weighted test statistics including Bauer-Kohne, Lehmacher-Wassmer, Cui-Hung-Wang; 3) Adjusted test statistics including Gao-Ware-Metha; 4) Promising zone including Chen-DeMets-Lan, Metha-Pocock, Liu-Hu, and Jennison-Turnbull; 5) Stepwise interval adjustment (to avoid back-calculation).
Sample Size Calculator	 PoC	
Error Rate Controller	 PoC	
Analytic Intelligence		


Rates Evaluator	 45%	<p>Online and Local Apps for Analyses of Rate(s).</p> <p>Upcoming: Perform 1) Asymptotic (Wald, Agresti-Coull), Likelihood (Wilson, Hybrid Wilson Brown, Likelihood Ratio), Exact (Clopper-Pearson, Wang-Chang, Mid-P, Blaker), and other (Equal-tailed Jeffreys, Bayesian MOVER, Garwood, Logit, Arcsine) methods for single rate; 2) Asymptotic (Wald, Wald CC, Agresti-Caffo, Hauck-Anderson), Likelihood (Mee, Miettinen-Nurminen, Farrington-Manning, Newcombe, Newcombe CC, Laud-Dane or Miettinen-Nurminen-Brown-Li, Gart-Nam), Exact (Fisher, Santner-Snell, Chan-Zhang), and other (Haldane, Jeffreys-Perks, Brown-Li Jeffreys) methods for comparison of two rates; 3) Rate ratio and odds ratio; 4) Exposure-adjusted rate.</p>
Meta Synthesizer	 PoC	
Bland-Altman Evaluator	 8%	<p>Local Apps for Bland-Altman Analysis.</p> <p>Upcoming: Perform the Bland-Altman Method for consistency assessment.</p>
eDISH Analysis	 PoC	
Data Management		
EDC Trialer	 43%	<p>Self-host app for Electronic Data Capture System.</p> <p>How to Access: Please contact help desk for instruction.</p>
MedDRA Coder	 88%	<p>Local App for Medical Term Coding according to MedDRA.</p> <p>V0.1_20240527: Perform the Weighted Ratio Matching (Token Sort, Token Set, and Partial Ratio) for medical term auto-coding; Customize MedDRA version.</p> <p>V0.2_20250302: Add the Public / Organizational / Personal Synonym Library; Add Adaptive Number Re-supply (per demand).</p> <p>V0.3_20251216: Fix bugs; Add the auto-filling for searching outcome; Add the Non-major SOC.</p> <p>Upcoming: Comply with the CDSIC Standard for submission readiness.</p>
WHODD Coder	 PoC	




Clinical Pharmacology

ITEM	STATUS	LOGS
Quantitative Pharmacology		

Non-compartmental Modeler	 34%	Local Apps for Non-compartmental Model Analysis. Upcoming: Perform relevant data handling convention (logarithm, time course specification, BQL); summarize and visualize time-concentration relationship; the Non-compartmental analysis ; CDISC compliance.
Compartmental Modeler	 PoC	
Population PKPD Modeler	 6%	Local Apps for Population PKPD Analysis. Upcoming: Perform relevant data handling convention (merge multiple source); the Non Linear Mixed Effect Model ; CDISC compliance.
PKPD Simulator	 PoC	
Concentration-QTc Model	 PoC	
Bioequivalence		
Bioequivalence Evaluator	 41%	Local Apps for Bioequivalence Analysis. Upcoming: Perform sample size calculation and power analysis ; Mixed Effect model for Bioequivalence assessment; CDISC compliance.
In-vitro and In-vivo Correlation (IVIVC)	 PoC	
Immunogenicity Assessment		
Immunogenicity Cut Points Calculator	 16%	Local Apps for Immunogenicity Cut Points Calculation. Upcoming: Perform Immunogenicity Cut Points Calculation .

Others

ITEM	STATUS	LOGS
Randomization and Material Consumption		
IWRS Trialer	 37%	Self-host app for Iterative Web-based Response System. How to Access: Please contact help desk for instruction.

Material Consumption Simulator		<p>Online App for Clinical Material Consumption Simulation.</p> <p>V0.1_20251012: Perform Monte Carlo simulation with <u>the Uniform Participant-center Distribution</u> and <u>the Fixed Number Re-supply strategy</u>.</p> <p>V0.2_20251016: Add a lag time for <u>the Shipment Period</u>; Add <u>Adaptive Number Re-supply (per demand)</u>.</p> <p>V0.3_20251027: Fix bugs for re-supply; Optimize output with <u>the Ratio of Practical/Theoretical Consumption</u>; Add <u>Adaptive Number Re-supply (per stock level)</u>.</p> <p>V0.4_20251126: Add <u>the Blind Mode (mixture with alternative materials)</u> for re-supply.</p> <p>Upcoming: Add <u>the Unimodel Participant-center Distribution (1-1/k participants cluster in 1/k centers)</u>.</p>
Submission Readiness		
Data Submission Complier		
eCTD Submission Complier		

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