# Development Plan

- App Development Plan

# App Development Plan

## Biometrics

| ITEM | STATUS | LOGS |
|---|---|---|
| **Study Designer** | | |
| Dose Escalation Simulator |  | Online and Local Apps for Dose Escalation Designs.<br><br>**Upcoming**: Perform A+B, Rolling-Six, CCD, TPI, mTPI, mTPI2 / Keyboard, BOIN, TEQR, I3+3 and WW designs. |
| Proof of Concept Simulator |  | Online and Local Apps for Proof of Concept Designs.<br><br>**Upcoming**: Perform Simons' Two Stage and Bayesian Continuous Monitor designs. |
| Group Sequential Calculator |  | Online and Local Apps for Group Sequential Designs.<br><br>**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 |  | Online and Local Apps for Sample Size Re-estimation Designs.<br><br>**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 |  | |
| Error Rate Controller |  | |
| **Analytic Intelligence** | | |

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|---|---|---|
| Rates Evaluator | 45% | Online and Local Apps for Analyses of Rate(s).<br><br>**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. |
| Meta Synthesizer | PoC | |
| Bland-Altman Evaluator | 8% | Local Apps for Bland-Altman Analysis.<br><br>**Upcoming**: Perform the Bland-Altman Method for consistency assessment. |
| eDISH Analysis | PoC | |
| **Data Management** | | |
| EDC Trialer | 43% | Self-host app for Electronic Data Capture System.<br><br>**How to Access**: Please contact help desk for instruction. |
| MedDRA Coder | 88% | Local App for Medical Term Coding according to MedDRA.<br><br>**V0.1_20240527**: Perform the Weighted Ratio Matching (Token Sort, Token Set, and Partial Ratio) for medical term auto-coding; Customize MedDRA version.<br><br>**V0.2_20250302**: Add the Public / Organizational / Personal Synonym Library; Add Adaptive Number Re-supply (per demand).<br><br>**V0.3_20251216**: Fix bugs; Add the auto-filling for searching outcome; Add the Non-major SOC.<br><br>**Upcoming**: Comply with the CDSIC Standard for submission readiness. |
| WHODD Coder | PoC | |

# Clinical Pharmacology

| ITEM | STATUS | LOGS |
|---|---|---|
| **Quantitative Pharmacology** | | |

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|---|---|---|
| Non-compartmental Modeler |  | Local Apps for Non-compartmental Model Analysis.<br><br>**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 |  | |
| Population PKPD Modeler |  | Local Apps for Population PKPD Analysis.<br><br>**Upcoming**: Perform relevant data handling convention (merge multiple source); the Non Linear Mixed Effect Model; CDISC compliance. |
| PKPD Simulator |  | |
| Concentration-QTc Model |  | |
| **Bioequivalence** | | |
| Bioequivalence Evaluator |  | Local Apps for Bioequivalence Analysis.<br><br>**Upcoming**: Perform sample size calculation and power analysis; Mixed Effect model for Bioequivalence assessment; CDISC compliance. |
| In-vitro and In-vivo Correlation (IVIVC) |  | |
| **Immunogenicity Assessment** | | |
| Immunogenicity Cut Points Calculator |  | Local Apps for Immunogenicity Cut Points Calculation.<br><br>**Upcoming**: Perform Immunogenicity Cut Points Calculation. |

# Others

| ITEM | STATUS | LOGS |
|---|---|---|
| **Randomization and Material Consumption** | | |
| IWRS Trialer |  | Self-host app for Iteriative Web-based Response System.<br><br>**How to Access**: Please contact help desk for instruction. |

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