

Rising to Excellence – How a China CRO Achieves International Standards

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Outline

- Selecting excellent staff
- Training staff to consistently meet customer requirements for quality and on-time delivery
- Retaining staff in a hot labor market
- Rapidly growing business while improving customer satisfaction
- Handling quick-turn projects

Selecting Excellent Staff

- Build relationships with universities. Identify top students for internships
- Sponsor education programs and events to link universities with industry needs
- Select only top 20% external recruiters
- Screen and interview with written tests for technical, computer, communication and language skills. Differentiate:
 - Entry level
 - Mid level
 - Managers and higher

Customized and Specialized Training

- SOP and WPD
- Industry standards and regulation training
- Project training and experience sharing
- Technical English
- Technical seminars from local universities and subject matter experts
- Internal journal and book club
- Shanghai and Beijing Biostat Forum, SAS Users Group, CDISC

Building the China Team

- Identify candidates
 - With strong work ethic
 - Eager to learn and quick to learn
- Challenges
 - Finding candidates with global experience and local know-how
 - Different values and culture
 - High employee turnover rate
- Achieve international standards by enforcing process and leadership

Retaining the China Team

- Maintain backlog of projects
- Competitive salary and benefits
- Support high-performers obtain further education
- Short-term training at clients' overseas sites
- Performance driven evaluation system
- Attractive training programs for career development

Expand Rapidly While Improving Quality

- Go extra mile to satisfy clients
 - Assign staff with high sense of urgency to quick turn projects
 - Rapidly grow staff to meet urgent needs
 - Use Tigermed resources for back-up
 - Tightly watch and control quality for urgent studies
- Clinical trial knowledge reinforces the quality of work
- Flexibility for non-standard work

Continuously Improving Quality

- Always follow SOP and Good Practice guidelines. Check and audit.
- Programming QC
 - Always double programming and peer review
 - Compare original and validation results. Complete WPD form for consistency check
 - QC documentation details in WPD forms
 - Review logs, run logcheck macro to ensure clean log
 - Sign PQRT
 - Quality control gate: Time sequence (e.g., TFL after ADS), QC documents completed and signed

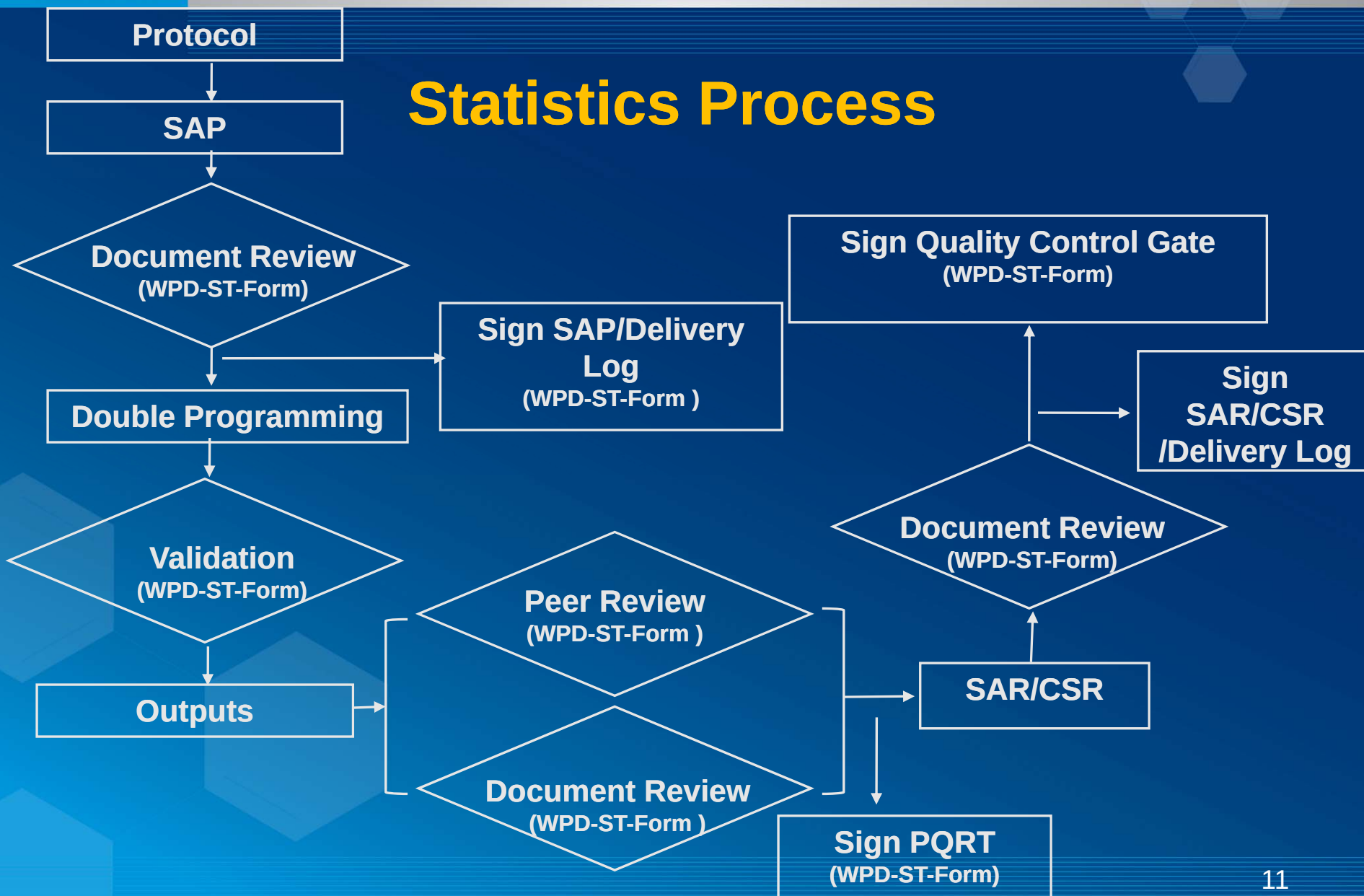
Continuously Improving Quality

- Documentation QC
 - QC SAR (report) against SAP. Complete company WPD. Review Comment Log
 - QC ReadMe document versus SAP
- External QC
- Follow clients' QC process
- *"Trust but verify"*

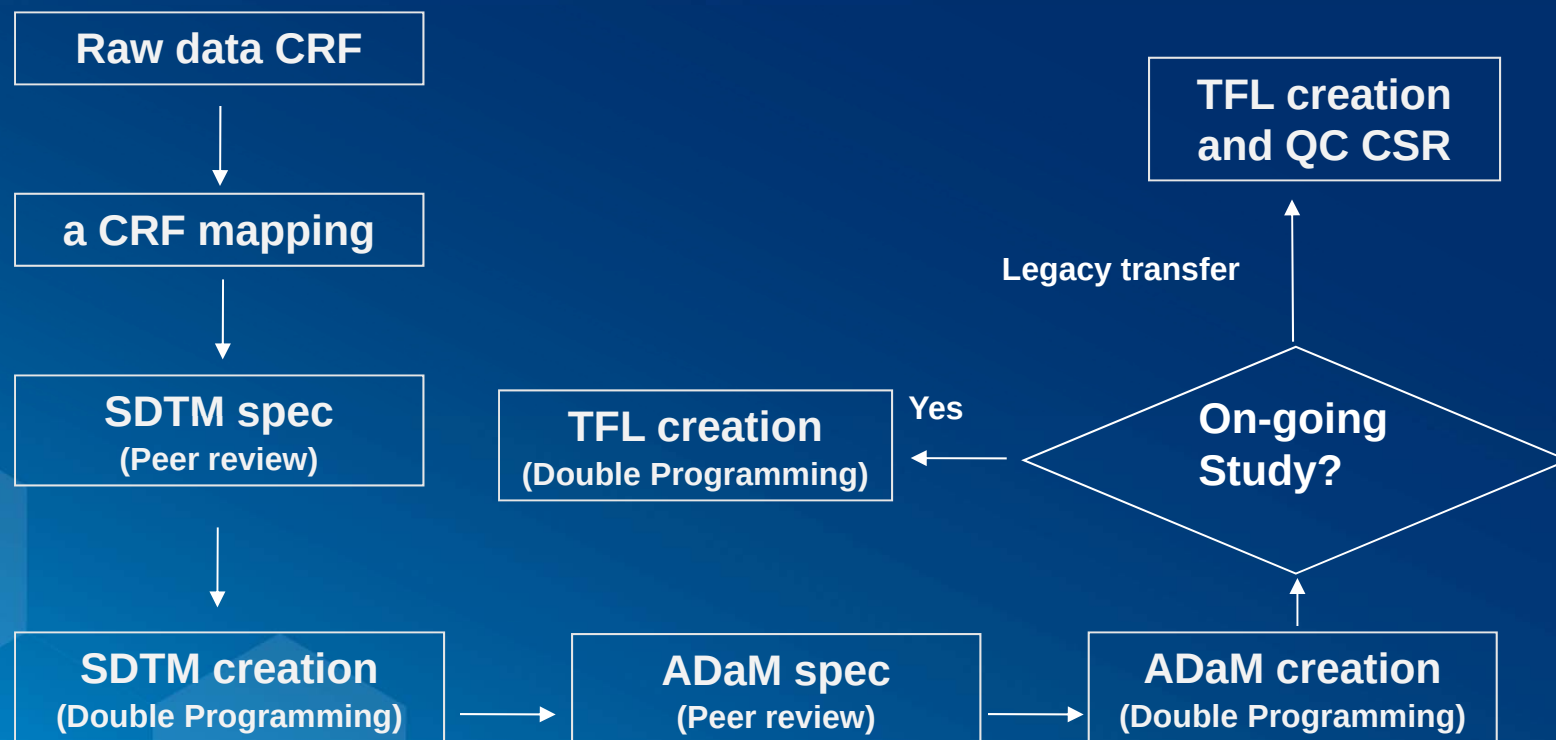
MacroStat as a Case Study

- Process driven
- Align staff's motivation to achieve business goals. Cascade goals through managers down to each employee.
- Effectively evaluate each employee at least semi-annually
- Communicate clear job expectations and promotion guidelines
- Effective leadership by role models
- After over 6 years of operation, MacroStat is the largest and strongest CRO in China

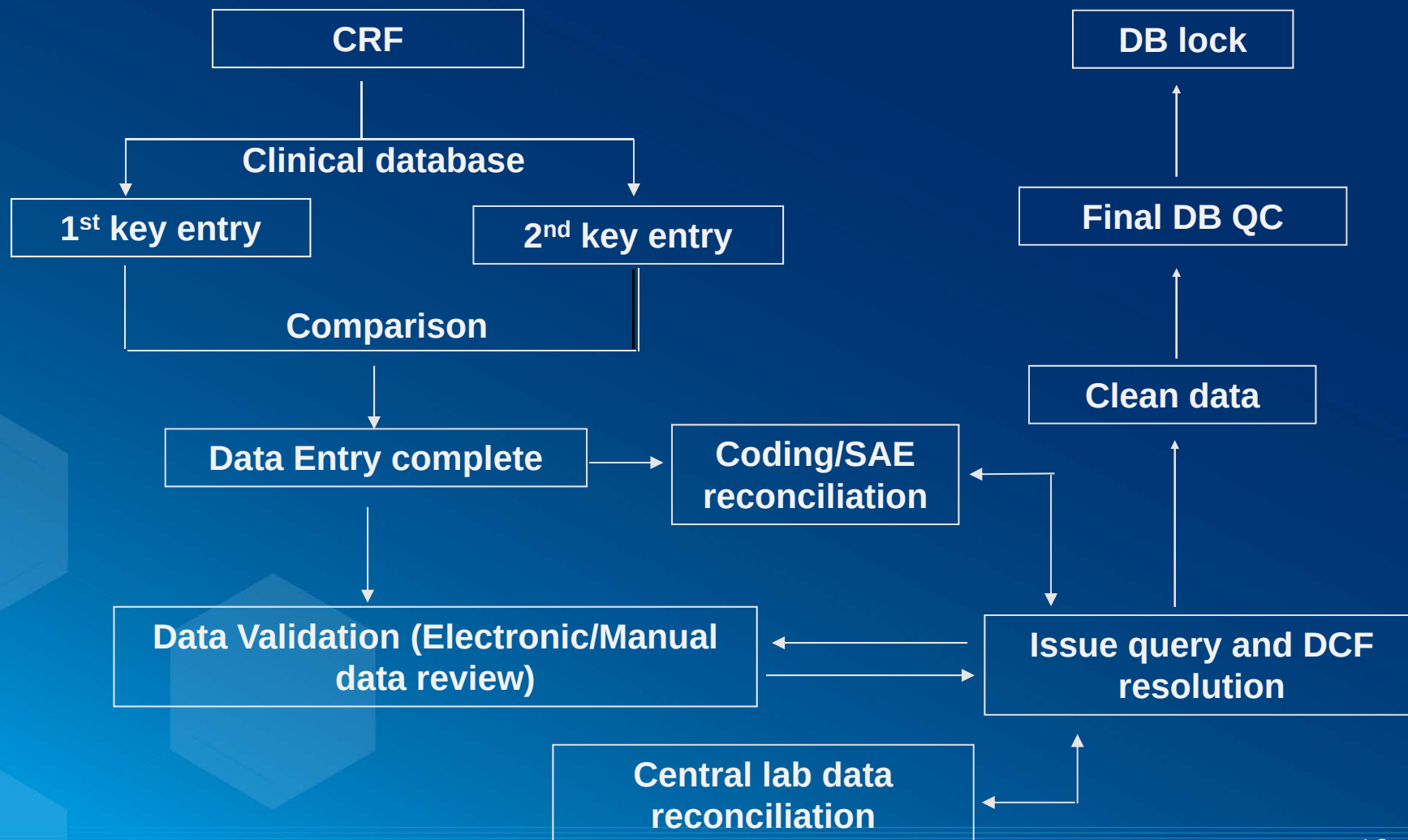
Statistics Process



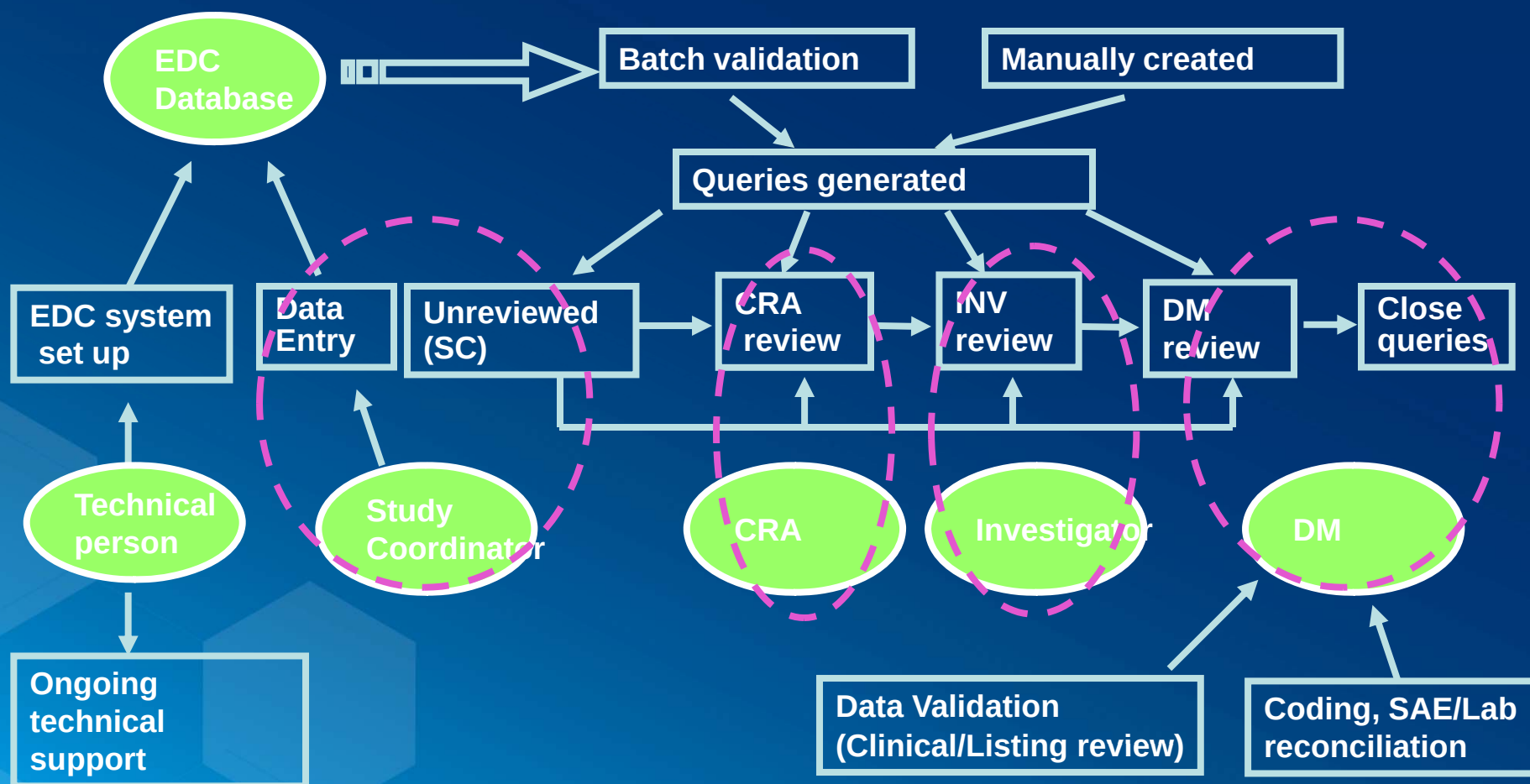
CDISC Work Process



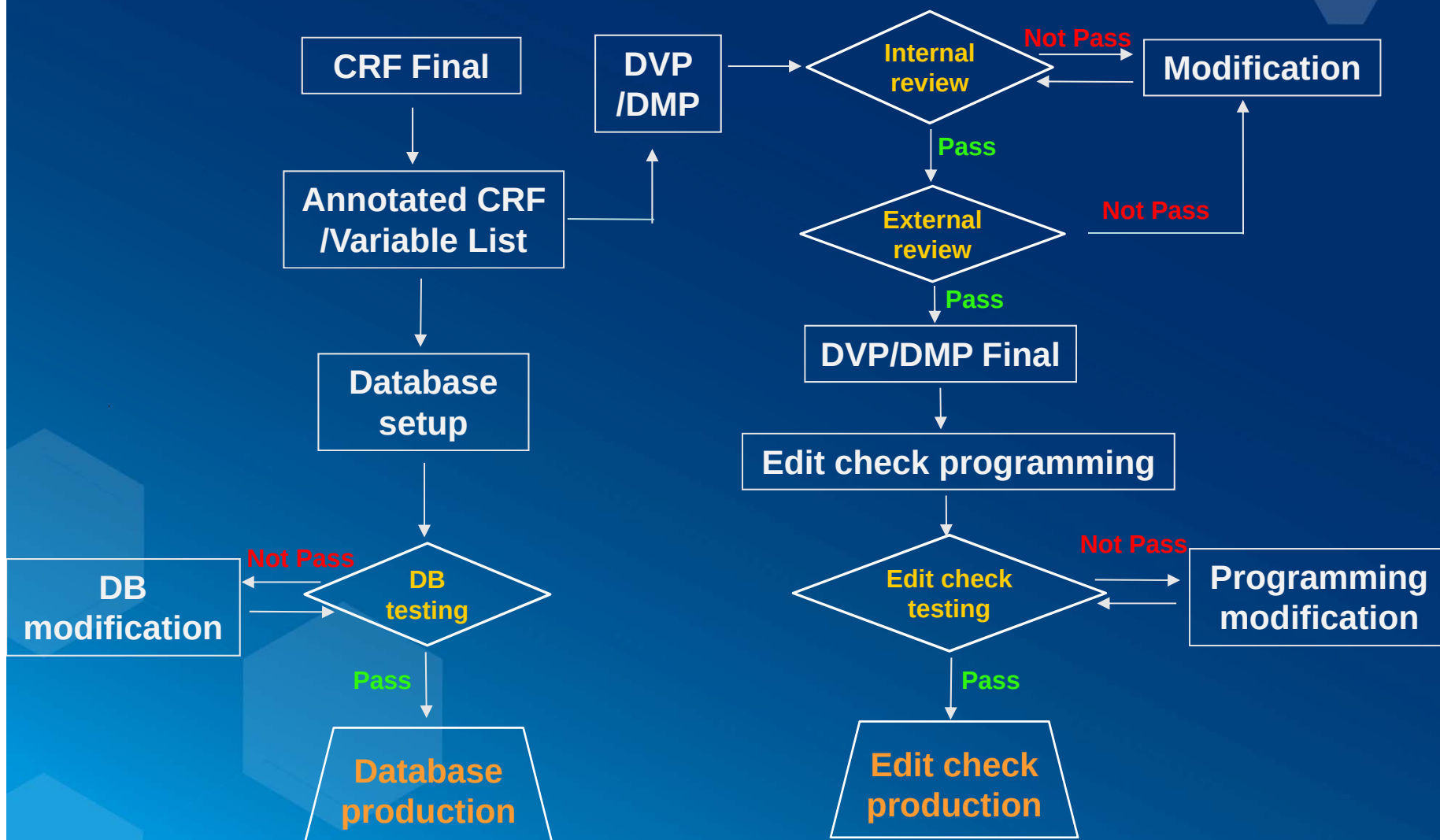
Data Management Process



DM Process (EDC)



DM Document Development Process



Standard Operating Procedures (I)

<u>SOP No.</u>	<u>Titles</u>
SOP-GA-01	SOP of SOP
SOP-GA-02	Deviations to SOPs
SOP-GA-03	Protecting Patient Privacy
SOP-GA-04	Physical Access Control
SOP-GA-05	Electronic Data Transfer
SOP-GA-06	Documentation and Archiving
SOP-GA-07	Final Deliverables
SOP-IT-01	Security Of System
SOP-IT-02	User And Computer Setup
SOP-IT-03	IT Helpdesk Request Process
SOP-IT-04	Information Technology System Maintenance
SOP-IT-05	Data backup and Restoration
SOP-IT-06	Disaster Recovery Plan

Standard Operating Procedures (II)

<u>SOP No.</u>	<u>Titles</u>
SOP-IT-07	Computer System Validation
SOP-IT-08	Validation Plan
SOP-IT-09	Design Qualification
SOP-IT-10	Installation Qualification
SOP-IT-11	Change Control
SOP-DM-01	DM Project Management
SOP-DM-02	CRF Design
SOP-DM-03	CRF Printing
SOP-DM-04	Database Setup
SOP-DM-05	Testing of Data Entry Interface
SOP-DM-06	Data Management Plan
SOP-DM-07	Data Validation Plan
SOP-DM-08	Testing of Electronic Edit Checks

Standard Operating Procedures (III)

<u>SOP No.</u>	<u>Titles</u>
SOP-DM-09	CRF Receipt and Tracking
SOP-DM-10	Data Entry and Comparison
SOP-DM-11	Data Review and Data Editing
SOP-DM-12	Query Generation, Tracking, and Resolution
SOP-DM-13	Medical Coding
SOP-DM-14	SAE Reconciliation
SOP-DM-15	External Central Lab Data Handling
SOP-DM-16	Database Quality Control
SOP-DM-17	Database Locking and Unlocking
SOP-DM-18	DM Trial Master File
SOP-DM-19	Local Lab Data Handling
SOP-DM-20	Data Extraction from DM System
SOP-ST-01	Statistical Project Management

Standard Operating Procedures (IV)

<u>SOP No.</u>	<u>Titles</u>
SOP-ST-02	Statistical Analysis Plan (SAP)
SOP-ST-03	Biostatistical Analytical Data Checks
SOP-ST-04	Generation of Analytical Database
SOP-ST-05	SAS Programming
SOP-ST-06	Quality Control
SOP-ST-07	Sample Size Calculation
SOP-ST-08	Randomization and Unblinding
SOP-ST-09	Interim Analysis
SOP-ST-10	Analysis Not Prospectively Planned
SOP-ST-11	Clinical Study Report
SOP-ST-12	DMC Analysis
SOPQ-04	Quality Assurance
SOPA-12	Translation Procedure

Standard Operating Procedures (V)

<u>SOP No.</u>	<u>Titles</u>
SOP DM-E-01	Managing a Rave Study
SOP DM-E-02	Rave System Maintenance and Management
SOP DM-E-03	eCRF Development in Rave
SOP DM-E-04	Data Validation Plan for a Rave Study
SOP DM-E-05	Programming and Testing of Edit Checks for a Rave Study
SOP DM-E-06	User Acceptance Testing of a Rave Study
SOP DM-E-07	Data Review and Management in Rave
SOP DM-E-08	Close a Rave Study

Working Practice Documents (I)

<u>WPD No.</u>	<u>Titles</u>
WPD-GA-01-01	Training
WPD-GA-01-02	Employee Records Management
WPD-GA-06-01	Document Naming and Version Control
WPD-IT-01-01	Workstation Security Policy
WPD-IT-01-02	Server Security Policy
WPD-IT-01-03	Security File Transfer
WPD-IT-01-04	Network Password Security Policy
WPD-IT-01-05	Access Control On File Server
WPD-IT-01-06	Access Control of Company
WPD-IT-01-07	VPN Account Control
WPD-IT-01-08	Projects Process on File Server
WPD-IT-01-09	Home BOC Deploy Plan
WPD-IT-02-01	Employee Setup

Working Practice Documents (II)

<u>WPD No.</u>	<u>Titles</u>
WPD-IT-02-02	Workstation Installation
WPD-IT-02-03	Workstation Setup
WPD-IT-02-04	User Network Account Setup
WPD-IT-02-05	Server Installation
WPD-IT-03-01	Contact the IT Helpdesk
WPD-IT-03-02	Borrowing IT Portable Equipment
WPD-IT-04-01	Server Monitoring
WPD-IT-04-02	Network Device Monitoring
WPD-IT-04-03	Computer Virus Monitoring
WPD-IT-04-04	Workstation Monitoring and Maintenance
WPD-IT-04-05	Server Room Environment Control
WPD-IT-04-06	IT Inventory List
WPD-IT-05-01	Data Backup

Working Practice Documents (III)

<u>WPD No.</u>	<u>Titles</u>
WPD-IT-05-02	Data Restoration
WPD-IT-05-03	Backup Data Testing
WPD-DM-04 -01	Access System Maintenance and training
WPD-DM-04 -02	Oracle Clinical System Maintenance and Training
WPD-DM-05-01	Testing of Data Entry
WPD-DM-08-01	Testing of Edit Checks
WPD-DM-09-01	CRF/DCF/MCF Tracking and Archiving
WPD-DM-10-01	Data Entry and Comparison in Access System
WPD-DM-10-02	Data Entry and Comparison in Oracle Clinical System
WPD-DM-11-01	Data Review and Data Editing
WPD-DM-11-02	Discrepancy Review and Data Editing in Oracle Clinical System
WPD-DM-12-01	Query Generation, Tracking and Resolution
WPD-DM-12-02	DCF Generation and Resolution in Oracle Clinical System

Company Policies

<u>Policy No.</u>	<u>Company Policy</u>
POL-001 V02	Employment Contract
POL-002 V01	Confidential Agreement
POL-003 V03	Employee Hand Book
POL-004 V02	Privacy Personally Identifiable Information
POL-005 V01	Office Security
POL-006 V01	Security Policy – Infosec Acceptable Use Policy in Home BOC for the 001-Client

Quality Control

- Staff required to follow SOP and Good Practice guideline
- Internal QC Process:
 - Programming QC
 - Always double programming and peer review
 - Compare original and validation results and fill out WPD form for consistency check
 - QC documentation details in WPD forms
 - Review logs, run logcheck macro to ensure clean log
 - Sign PQRT
 - Quality control gate: Time sequence (e.g., TFL after ADS), QC documents filled and signed
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- External QC
 - Follow clients' QC process

Our Achievements

- Over 7 years of successful collaboration with customers
- Largest Biometrics CRO in China
- Extraordinary and effective leadership team
- Increasingly agile. Consistently deliver service, quality, and value to international clients
- Passed all audits with no critical findings
- Internationally recognized for total customer satisfaction to earn repeat business



Q&A