# Clinical Data Management at Kendle

Symposium der gmds Projektgruppe
“Data Management in klinischen und wissenschaftlichen Studien”, 18. November 2005

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# Overview

- Kendle Overview
- Kendle Biometrics Structure
- Kendle CDM Systems
- CDM Project Management and Resources
- CDM Procedures
- Summary

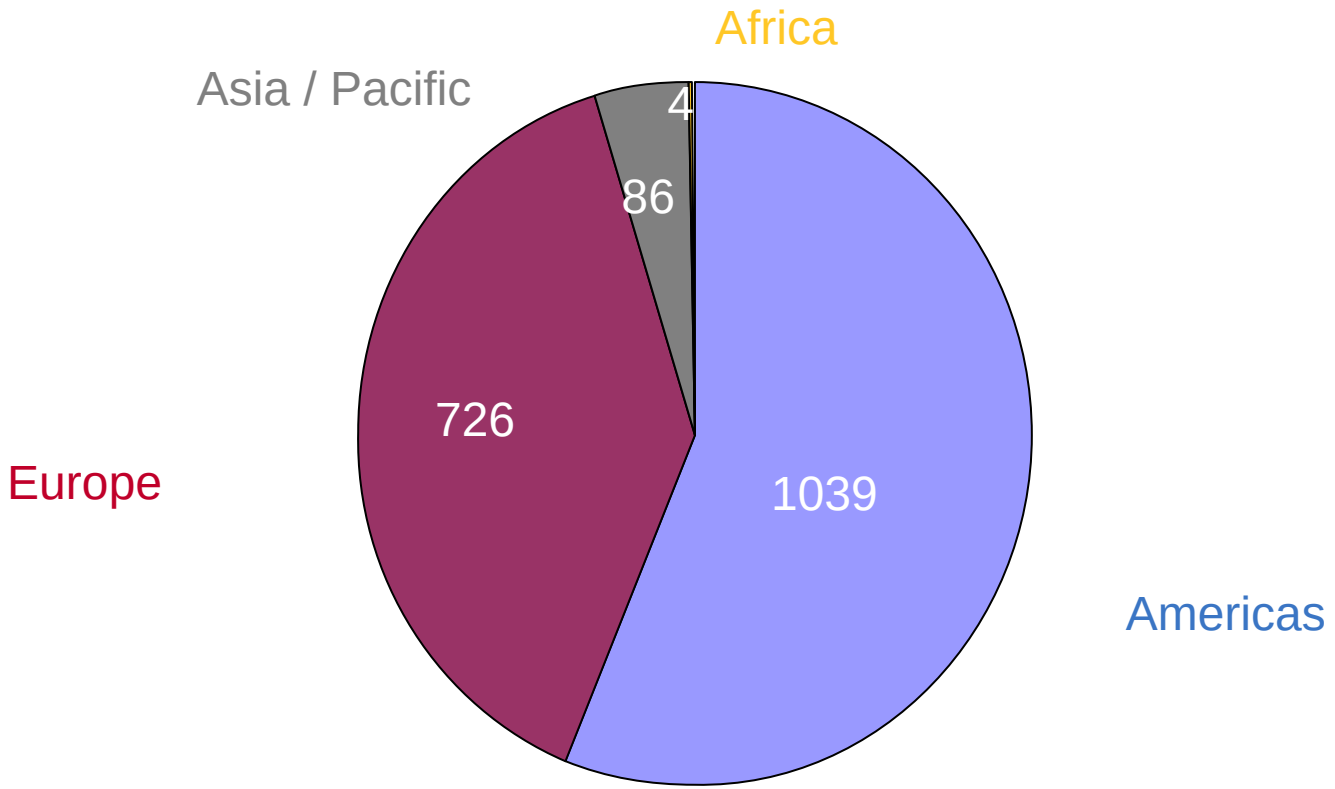
# Kendle Overview

# Company Overview

- Kendle founded in 1981
- Publicly-held clinical research organization
- 1,800+ associates worldwide
- Offices in North America, Latin America, Europe, Asia, Australia, South Africa, & India
- Global clinical trials conducted in 70 countries

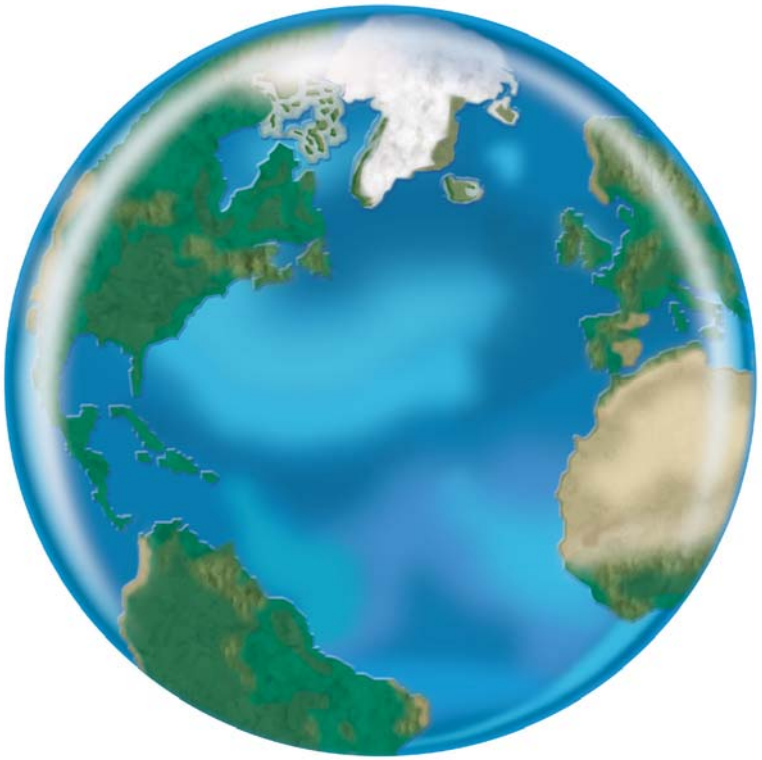
# Kendle Headcount

1855 ASSOCIATES



Kendle

# Kendle Office Locations



## North America

Chicago, IL
Cincinnati, OH
Cranford, NJ
Los Angeles, CA
Morgantown, WV
Old Lyme, CT
Rockville, MD

## Latin America

Lima (Peru)
Mexico City

## Asia / Pacific

Beijing (China)
New Delhi (India)
Melbourne (Australia)
Sydney (Australia)

## Europe

Barcelona (Spain)
Bucharest (Rom.)
Crowthorne (UK)
Ely (UK)
Milan (Italy)
Munich (Germany)
Paris (France)
Sofia (Bulgaria)
Utrecht (NL)
Warsaw (Poland)

## Africa

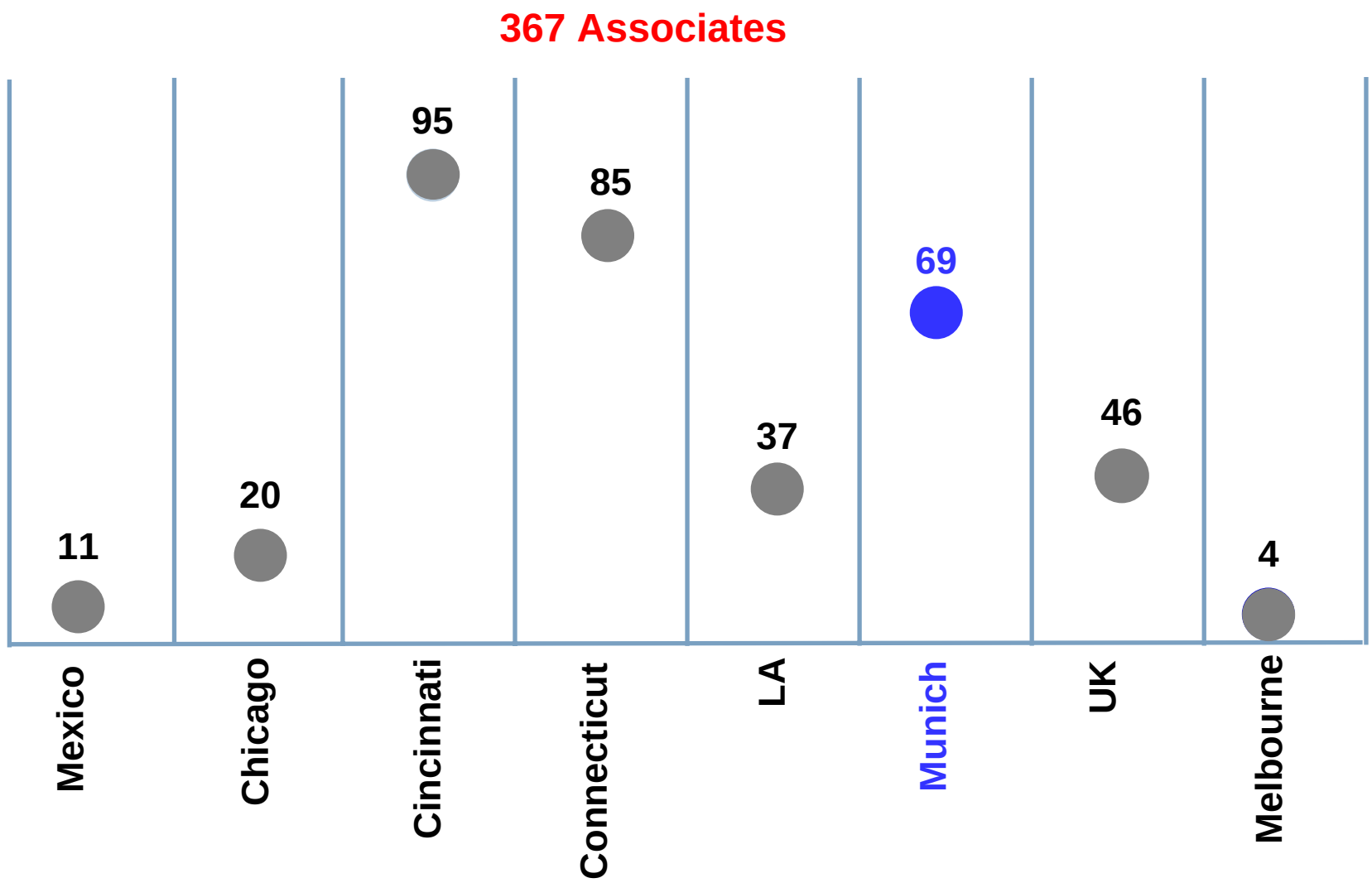
Johannesburg

# Core Services

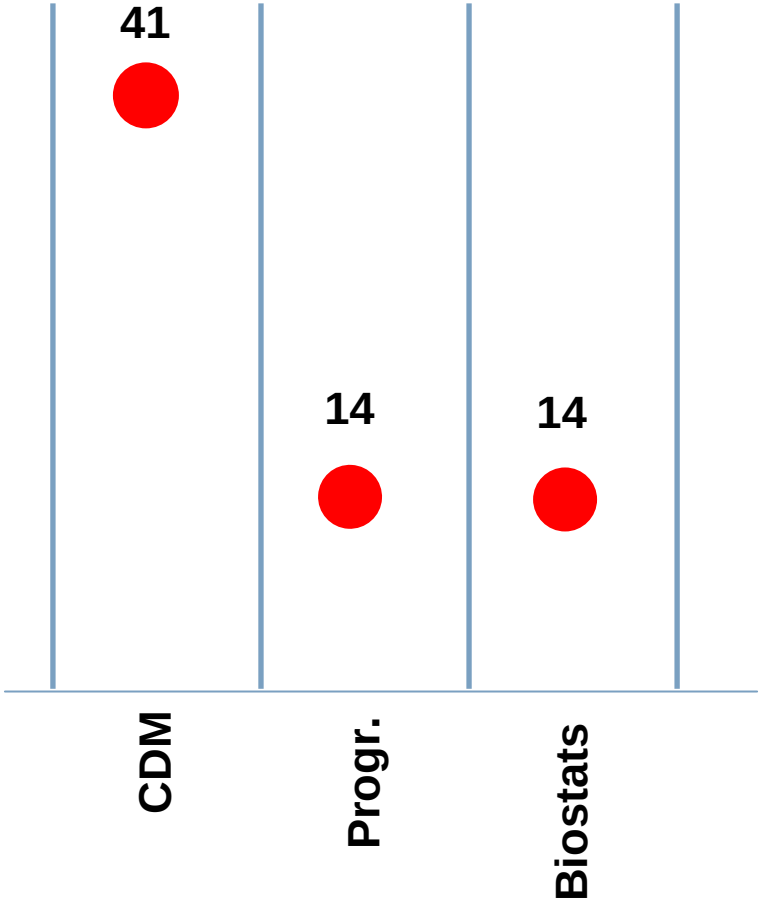
- Clinical Development – Phase I-III Clinical Research
- Global Regulatory Affairs – Consulting and Submission services validation and compliance, pharmacovigilance/safety
- Biometrics – Clinical Data Management, Biostatistics, Scientific Programming
- Late Phase Services – Phase IIIB/IV Studies, Health Economics Outcomes Research, Scientific Events, Education and Publications

# Kendle Biometrics Structure

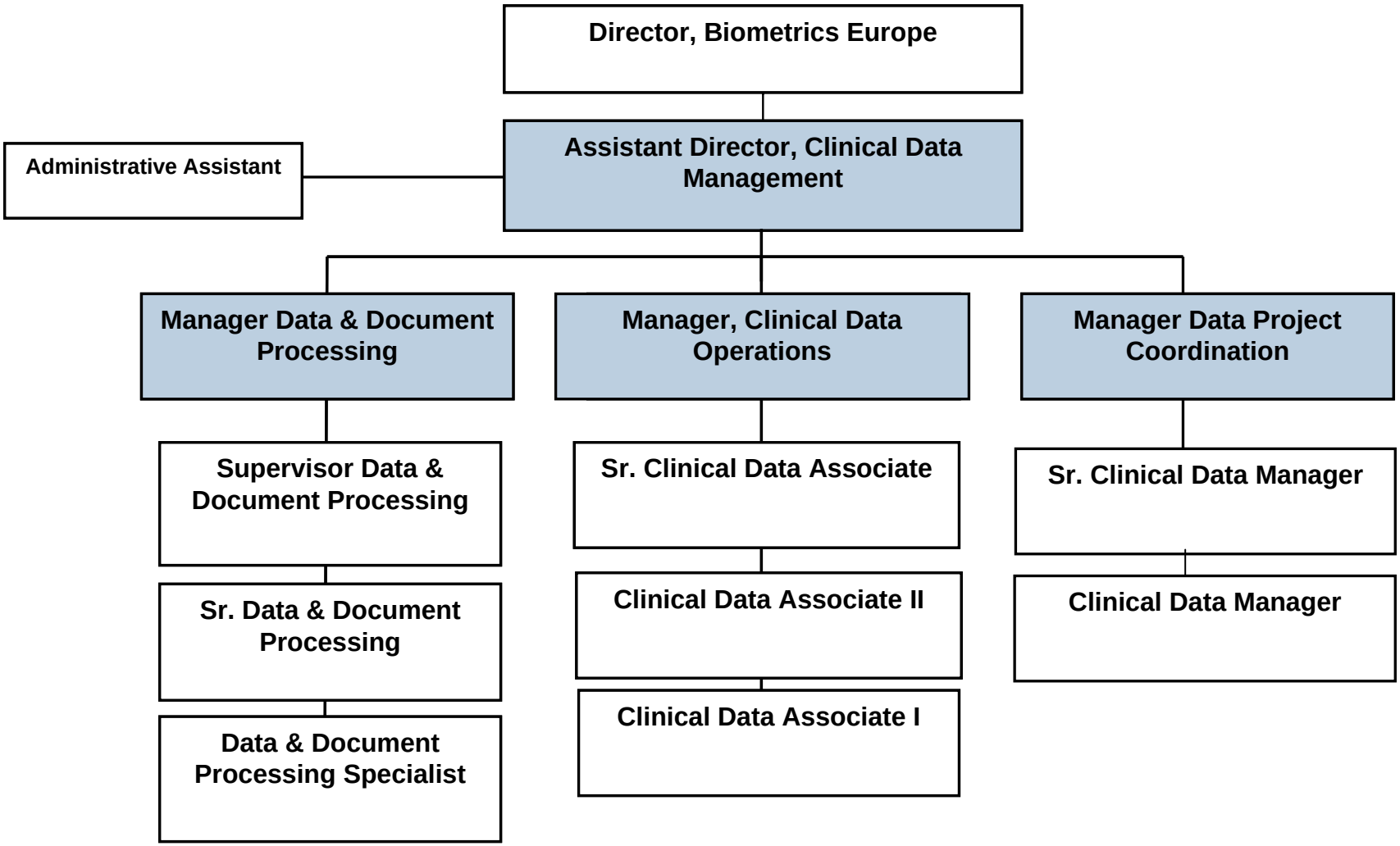
# Biometrics Global Resources



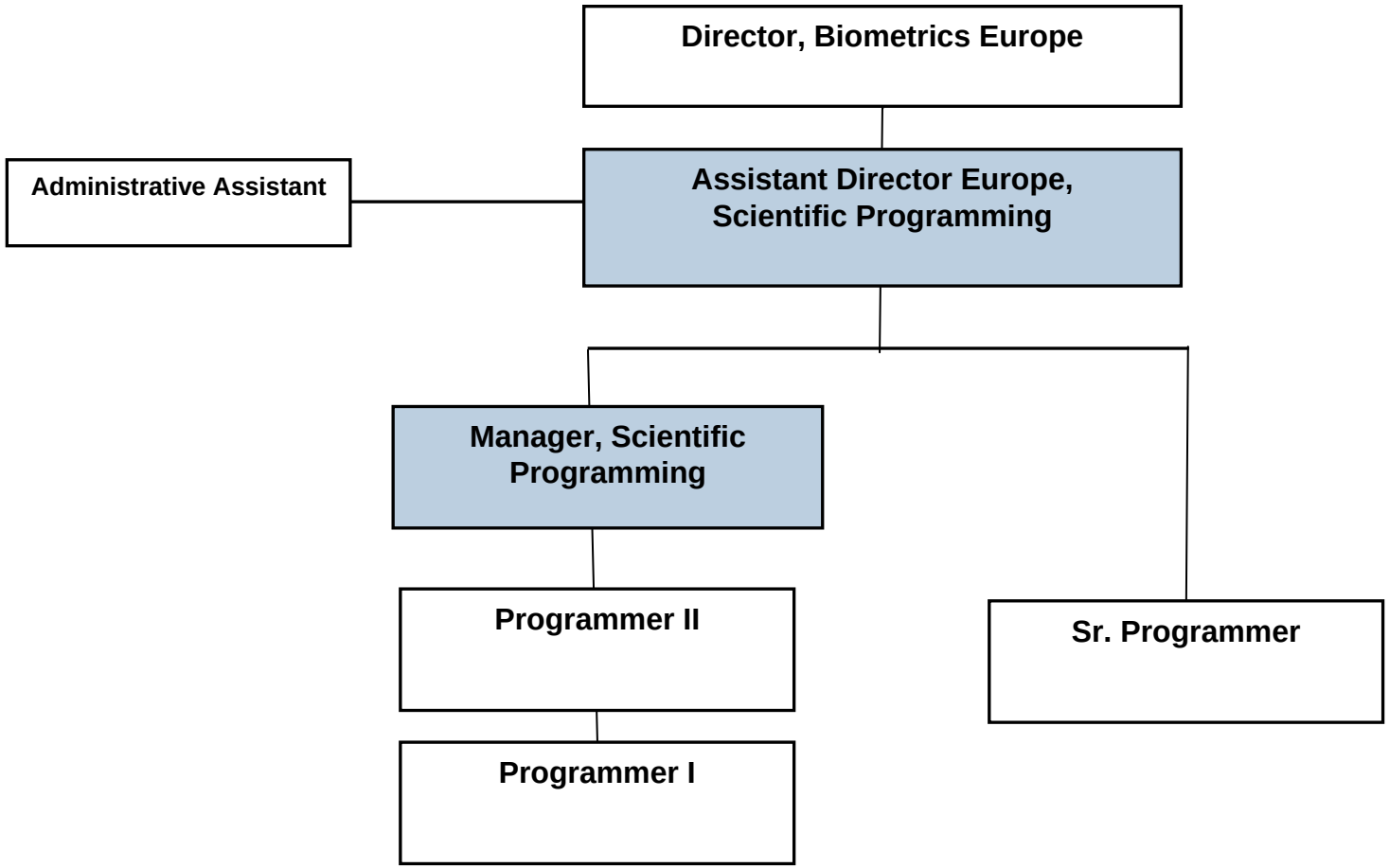
# Biometrics Resources in Munich



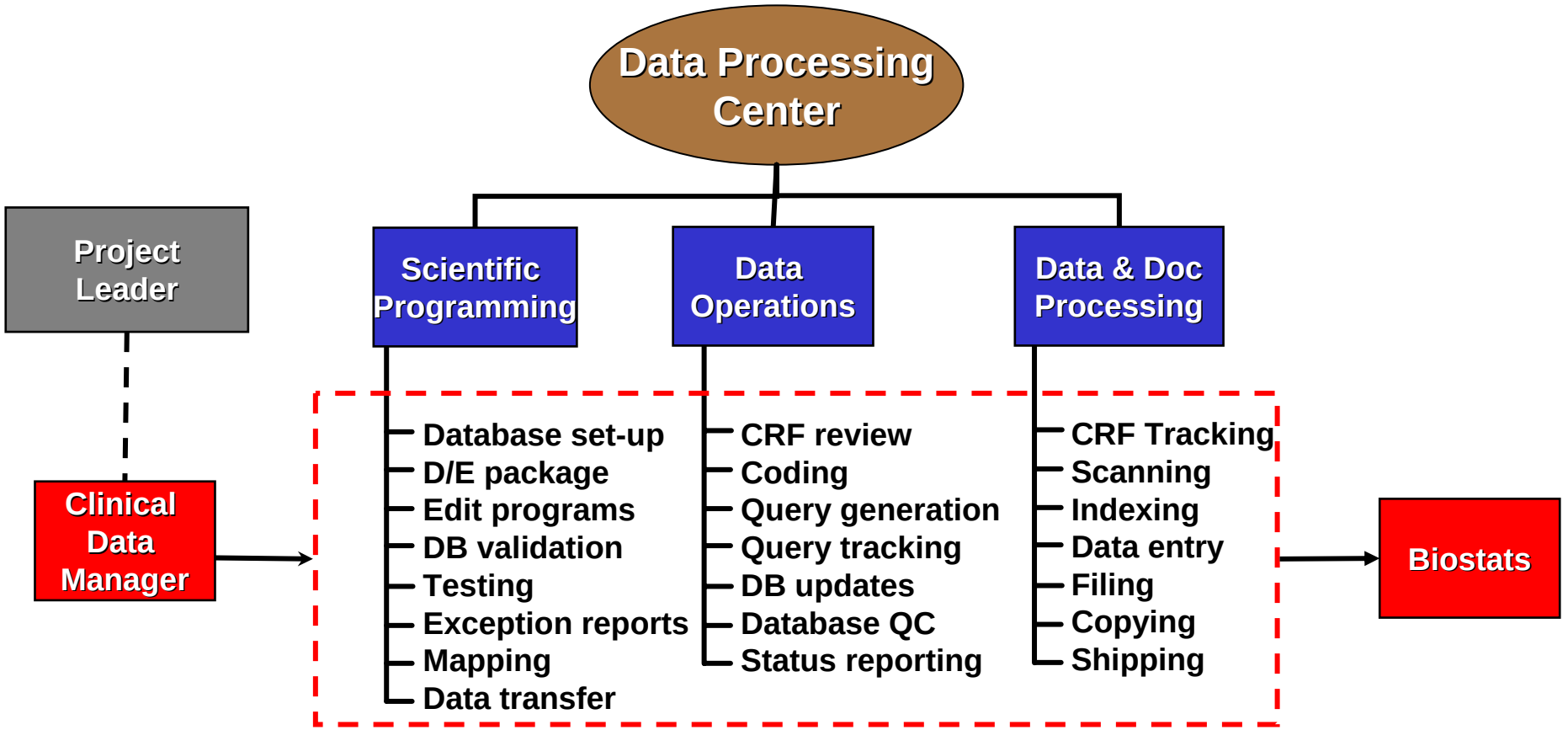
# Clinical Data Management, Munich



# Scientific Programming, Munich



# CDM / Programming Team



# Data Management Systems

- ✓ **Use TrialBase (TB)**
  - Kendle's global CDM system
  - Global SOPs, in-house training, target metrics
- ✓ **Use of EDC**
  - O*C RDC
  - PSOPs, specific training, metrics collected
  - Help desk to be set up
- ✓ **Via direct connection to client database**
  - Client database license(s)
  - Client SOPs, training and target metrics
- ✓ **For observational trials**
  - MS Access, TELEform, TrialGTS

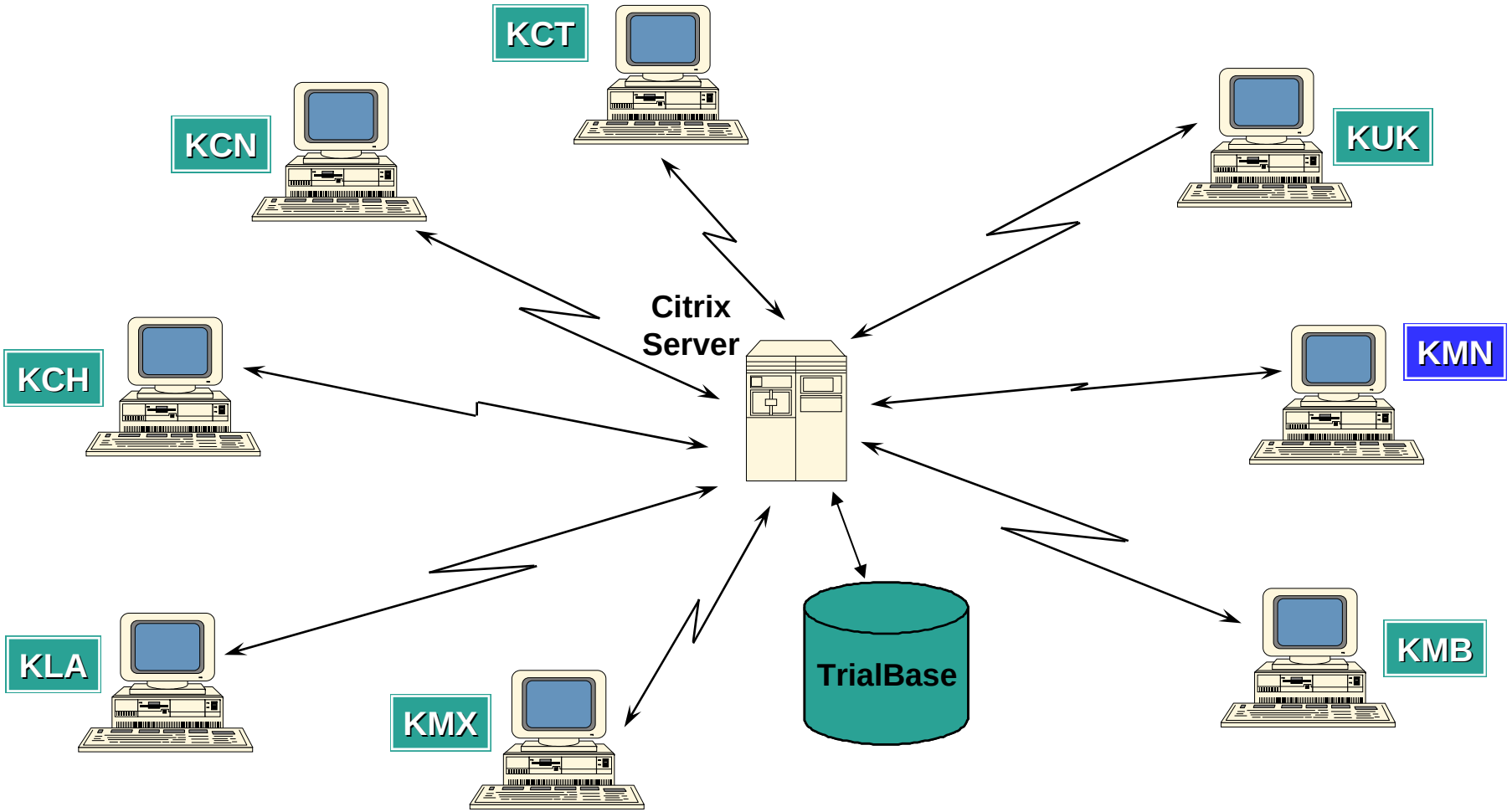
# Kendle's TrialBase System

# TRIAL BASE®

*proprietary technology tools*

- Developed by Kendle in ORACLE
- Flexible with rapid set-up
- CRF imaging -- automated workflow
- Electronic query management
- Global implementation
- Fully validated, Part 11 compliant

# Multi Site Processing



# Kendle's
# Remote Data Management Experience (RDM)

# Kendle Experience with RDM

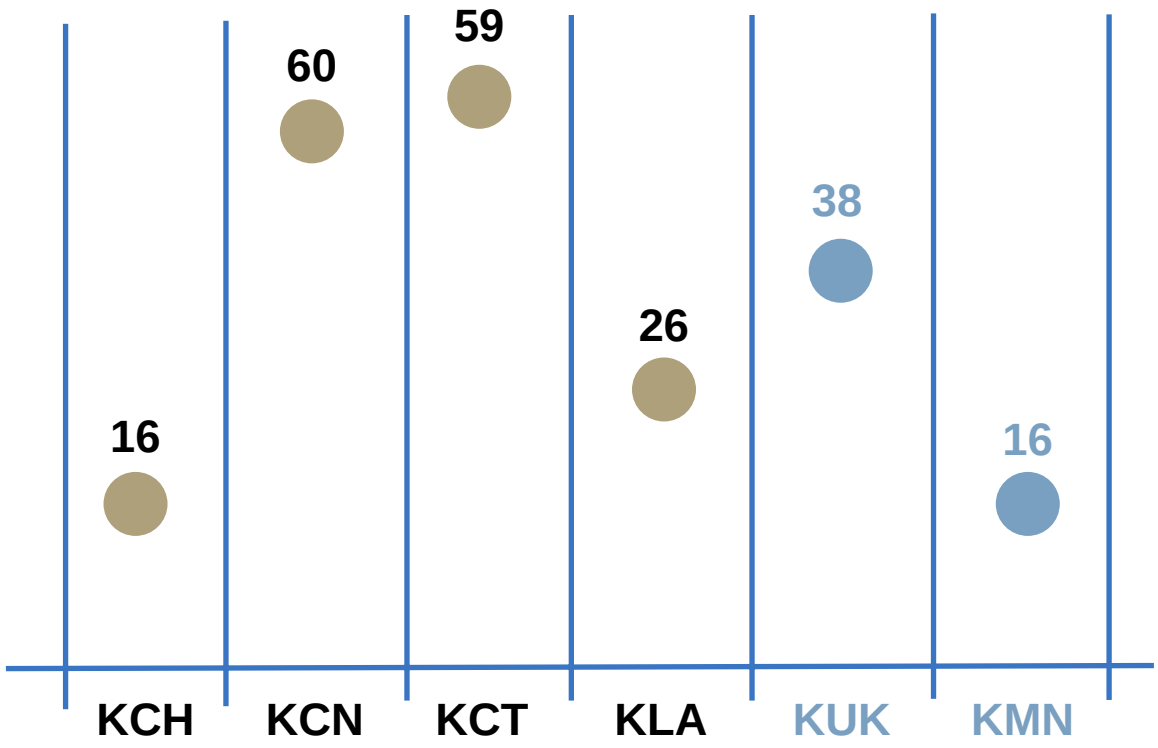
- First RDM studies carried out over 8 years ago
- 8 different clients for CDM services
- 6 different Kendle locations
- Clinical Data Management Systems accessed through RDM include:
  - Oracle Clinical, Oracle Clinical RDC
  - Clintrial
  - DLB Recorder
  - Other
- 250+ studies completed using this methodology

# Working in an RDM environment

- Client will have control, retaining ownership and will be able to monitor Kendle's progress
- Kendle will apply client's SOPs and working practices
- No interim/ final data transfers from Kendle to client required
- Client's statistical department is able to access the data as needed
- Shorter lead-time to work being placed
- Kendle associates can be managed as a flexible resource supplementing the client in house team

# OC Experience at Kendle

215 Associates



# Strategies to ensure success for RDM

- Technical
  - Integration of Kendle locations into Client technology infrastructure, with remote access to all necessary tools
  - Performance benchmarking
  - Helpdesk support with SLA (Service Level Agreement)
- Operational
  - Partnership in training
  - Clear responsibilities for Kendle and Client's staff
- Project Coordination
  - Workload prediction
  - Clinical System support

# From Request for Proposal (RFP) to Project Award

# From RFP to Project Award

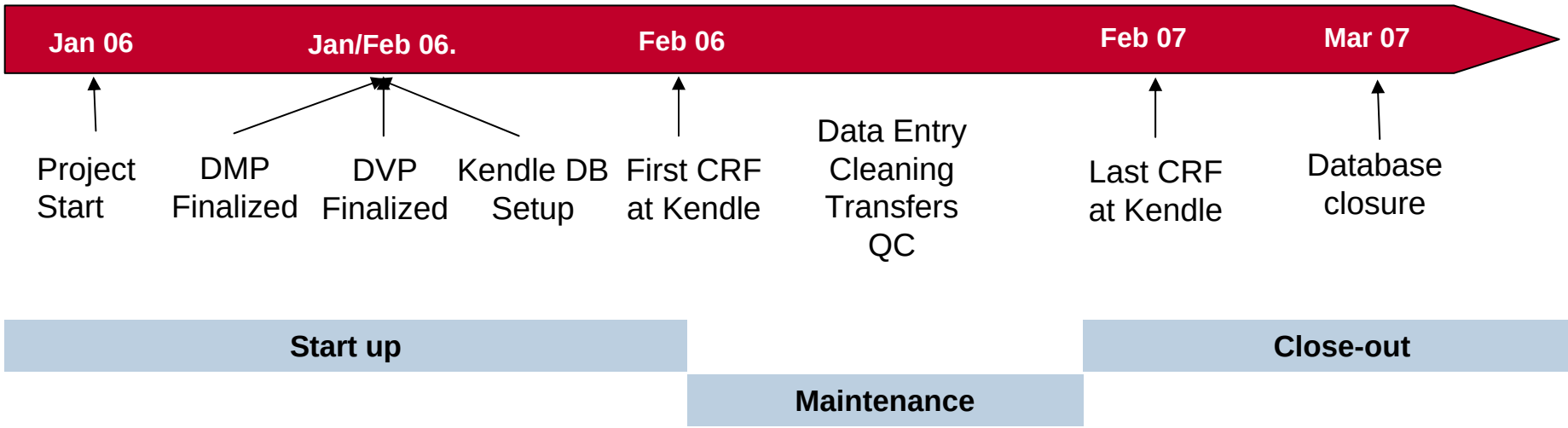
1. Request for proposal from client
2. Preparation of proposal by Kendle
3. Bid defense meeting with Kendle team and client
4. Project Award, preparation of contract
5. Project Kick-off Meeting –> Study start

# Project Management and Resources

# Kendle Biometrics Project Management

- Primary point of contact for both studies
- Communication plan between Client and Kendle
- Regular phone conferences
- Status reports provided every month
- Coordination of the Kendle Programming and CDM team
- Conduct of face to face meetings

# Key Timelines for the study - Example



# FTEs estimates - Example

| Role | Set-up | Maintainance | Close-out |
|---|---|---|---|
| Biometrics Project Leader | 1.5 | 0.3 | 0.5 |
| Clinical Data Associate* | <0.1 | 2.3 | 2.4 |
| Data Entry* | <0.1 | 3.5 | 0 |
| Programmer | 2.4 | 0.2 | 0.2 |

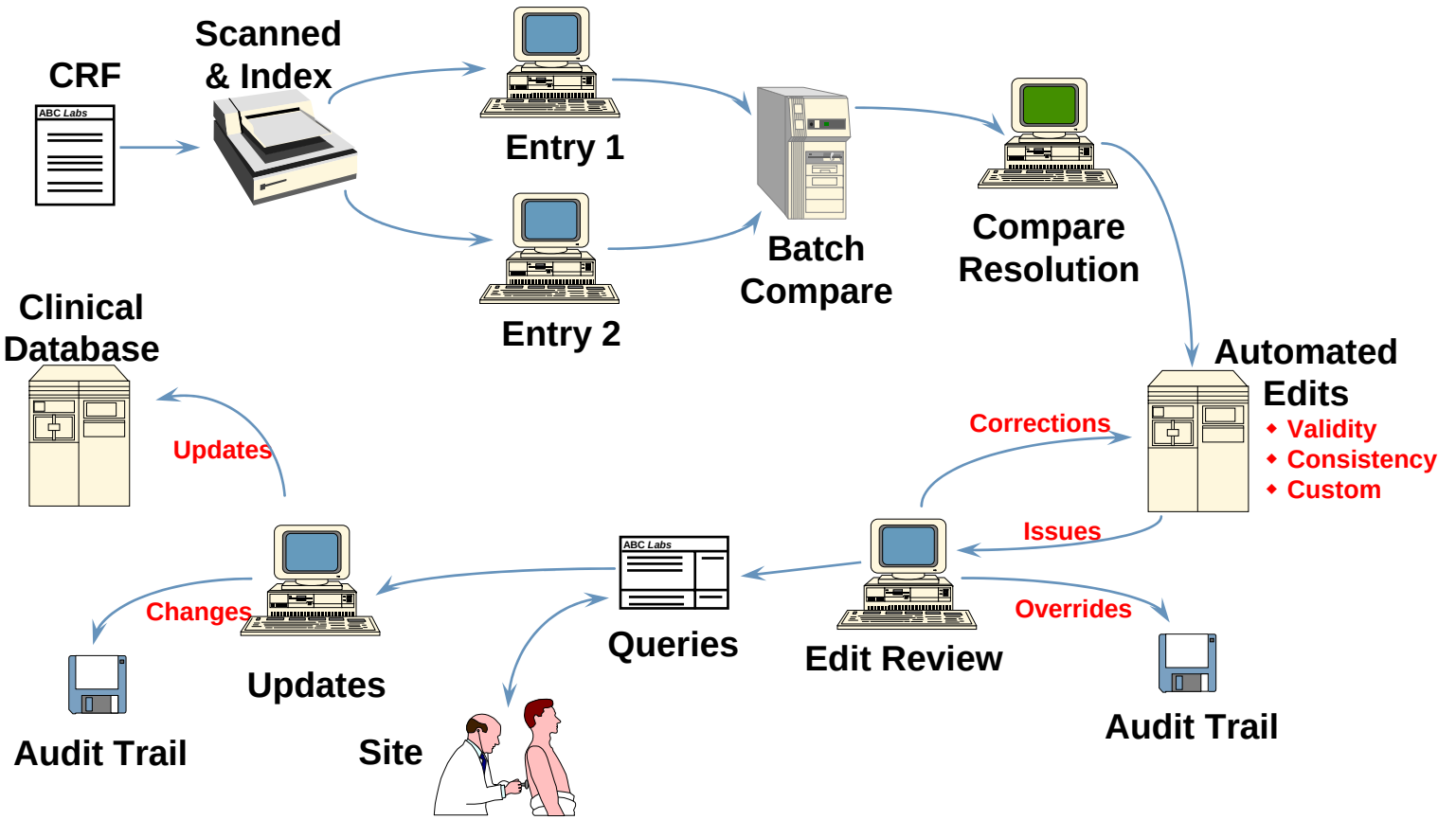
* Assuming continuous CRF / query flow

# CDM Procedures

# Data Management Plan

- Development in co-operation with Client
- Content of Data Management Plan:
  - Project communication, contacts
  - Database programming
  - CRF process flow
  - Data entry guidelines
  - Data cleaning including data validation plan
  - Regular status reports
  - Coding
  - Handling of external data
  - SAE reconciliation
  - Database quality control
  - Data transfer
  - Database closure

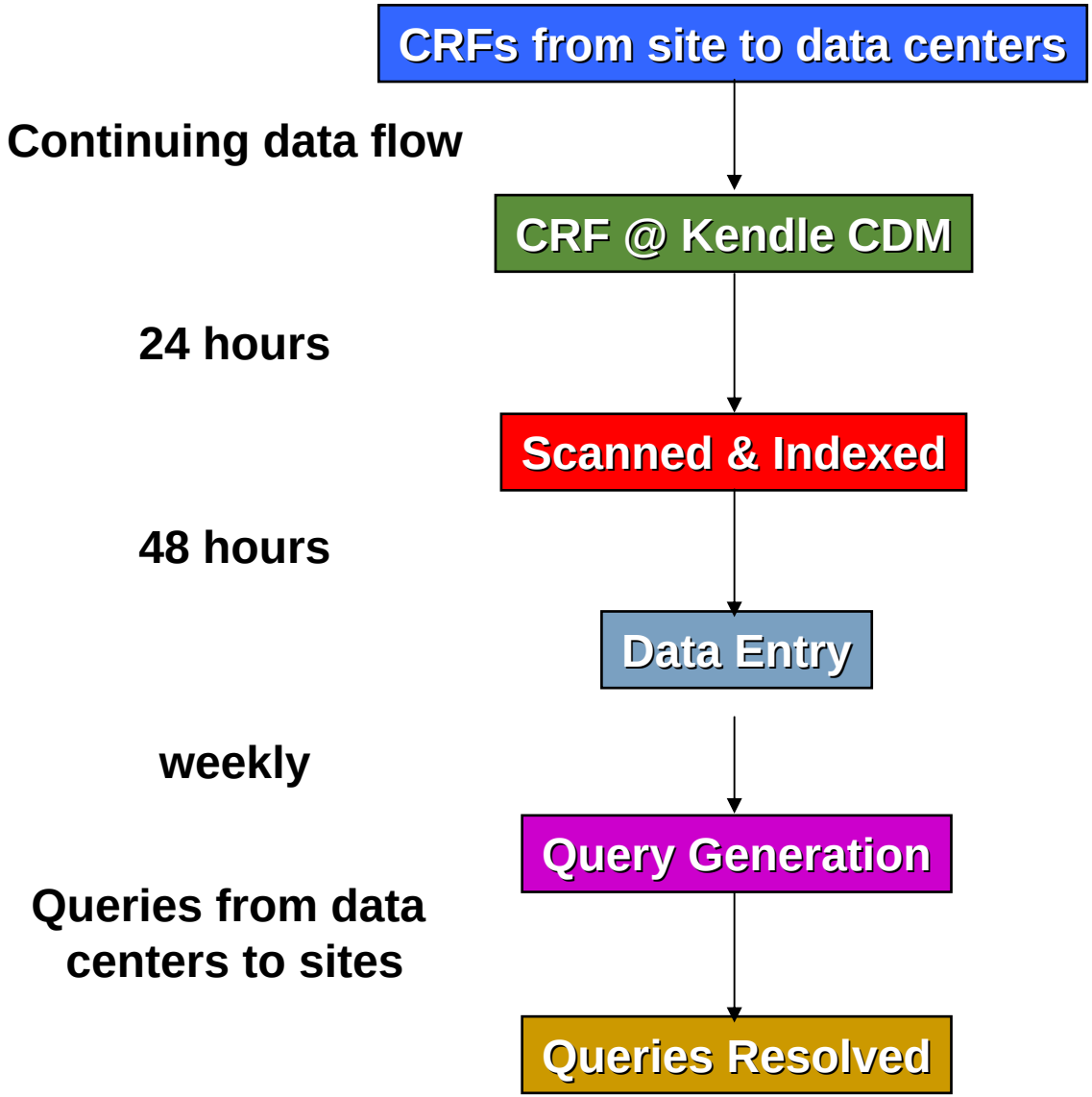
# TrialBase Work Flow



# Database Cleaning

- Development of Data Validation Plan in cooperation with  Client
- Edit programs run on a continuous basis
- Issues are reviewed by a CDA and in case a query generated
- Queries are provided to CRAs
- Database corrections are performed according to the answers of the investigators
- Corrections are tracked in an electronic audit trail

# Expedited CRF Data Flow



# Coding

- Assign coding dictionary
  - MedDRA for adverse events/symptoms
  - WHODRUG for medication
- Continuous auto-encoding performed
- Provide Client with coding listings for approval

# Reports

- Regular status reports are generated
  - CRF Status Report
  - Query Listing
  - Other
- Special reports for Data Monitoring Boards can be provided

# SAE Reconciliation

- Definition of the variables to be reconciled for the SAEs in the Safety database and the Kendle study database
- Safety provides Kendle CDM with the SAE reports from their database
- Kendle reconciles the SAEs and in case feedbacks discrepancies
- Client decides on the course of action, e.g. query to site
- Appropriate database corrections are performed
- SAE reconciliation before DB closure

# External Data

- Central laboratory, ECG data, electronic diaries etc.
- Regular transfer from the external providers to Kendle monthly
- Consistency checks as defined in the DVP
- Data will be imported into Client's database before database closure

# Database Closure Procedure

- The following steps have to be finalized before database closure
  - Data entry completed
  - Data cleaning finalized: last query resolved
  - Coding, SAE reconciliation completed
  - All external data received
  - Quality control passed
- Database closure reviewed and approved by Client
- Database closure documented and provided to Client

# Summary

# Summary

- Kendle has an experienced Biometrics project team
- SOPs for all processes in place
- Up front planning, risk assessment, issue awareness
- Kendle provides input for continuous improvement
- Resources available