excelya
excelling with care

CLINICAL DATA MANAGEMENT

WE MEET YOUR NEEDS

PEOPLE, PROJECTS, PASSION

RIGHT SIZE
European mid-size CRO focused on every client's individual needs. To deliver your data requirements we leverage our 15+ years data management expertise and service experience.

OUR OFFER
CHOOSE FROM ONE OF OUR READY-MADE MODELS

FULL SERVICE DATA MANAGEMENT	FUNCTIONAL SERVICE DATA MANAGEMENT: OPTIONS

#01
Data management team executes all activities during the study life cycle, from database setup to database lock

#02
Minimum 2 experienced Data Managers assigned per project to assure quality

#01
Operational Excellence Centre: Qualified people, ready to go

#02
Dedicated team to insert into your quality workflow

#03
CDISC standards to support cost-effective submissions

#04
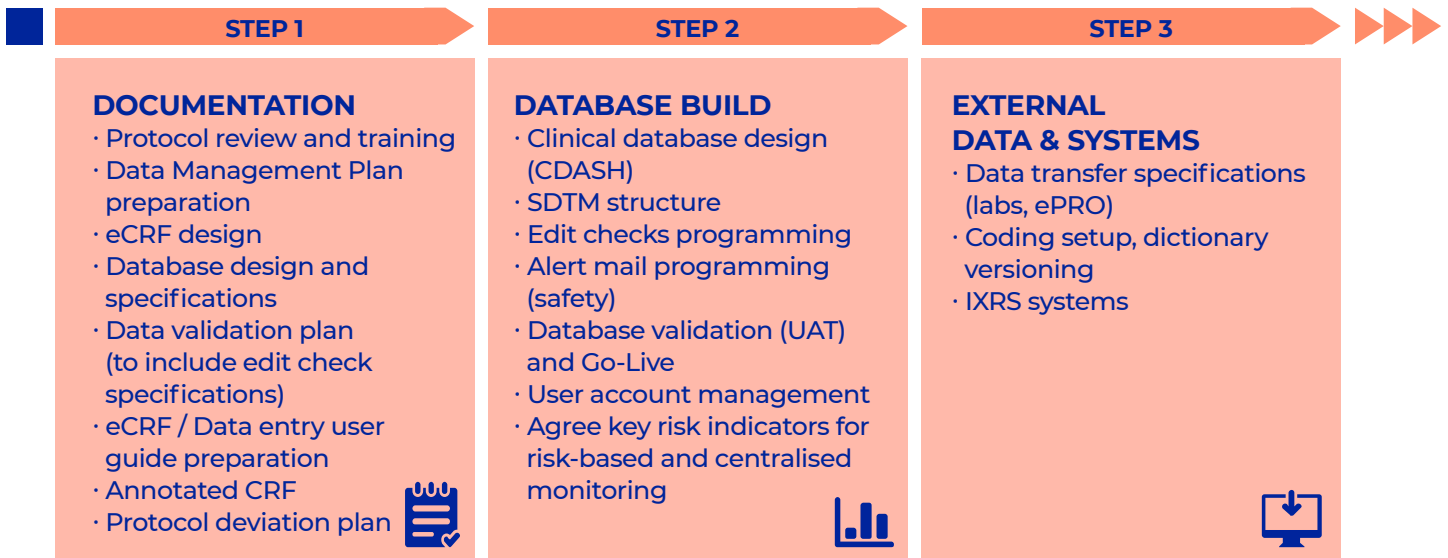Two Excelya database options to fit your needs

#03
Governance using agreed KPIs and targets to drive performance management
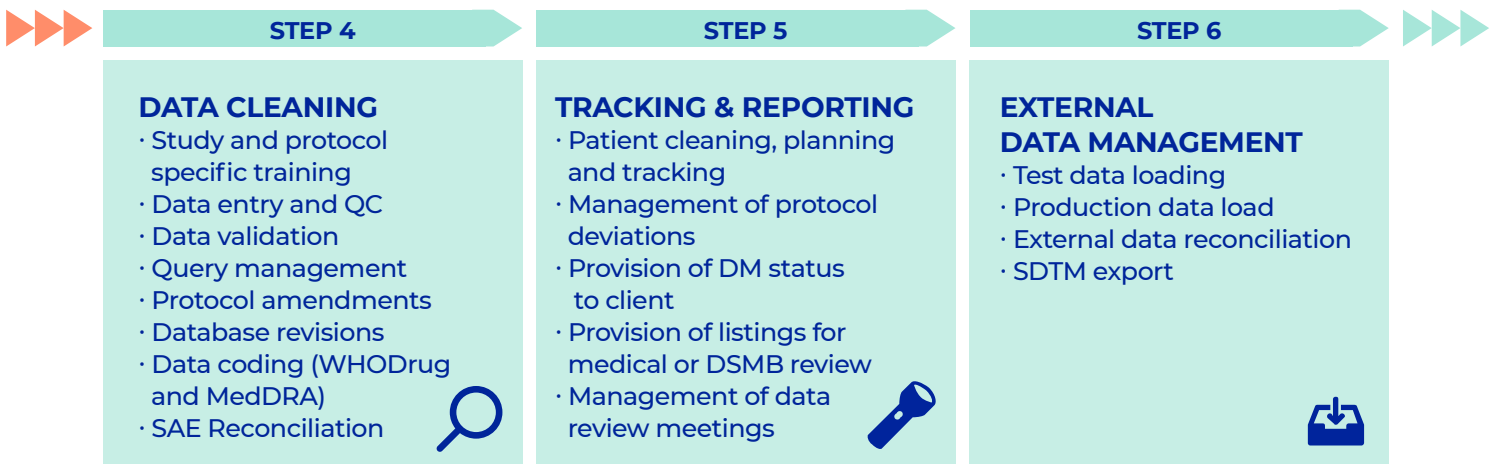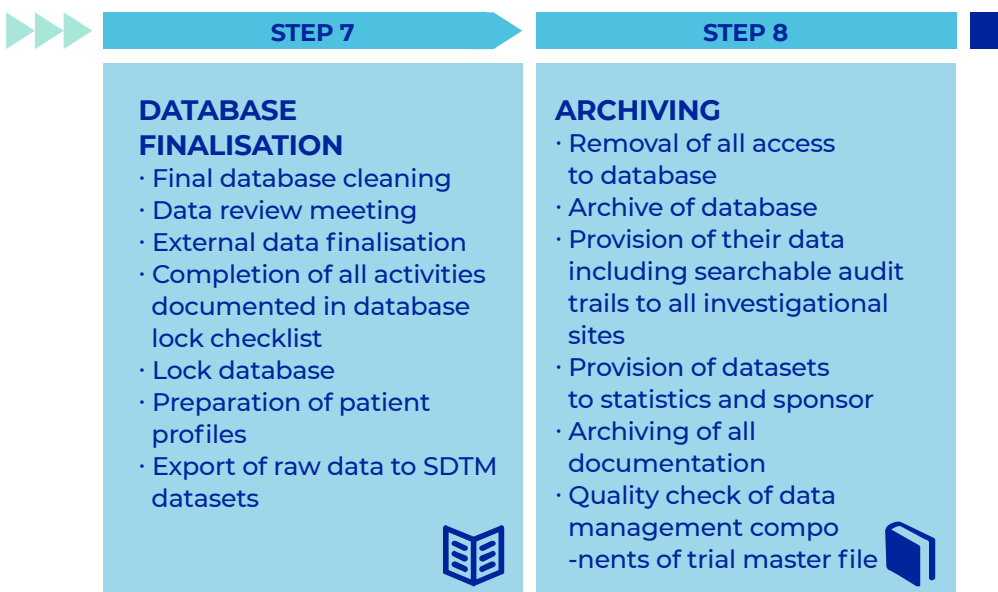
OR DESIGN YOUR OWN MODEL WITH OUR EXPERTS

Overviews

SET-UP OVERVIEW

STEP 1

DOCUMENTATION
· Protocol review and training
· Data Management Plan preparation
· eCRF design
· Database design and specifications
· Data validation plan (to include edit check specifications)
· eCRF / Data entry user guide preparation
· Annotated CRF
· Protocol deviation plan

STEP 2

DATABASE BUILD
· Clinical database design (CDASH)
· SDTM structure
· Edit checks programming
· Alert mail programming (safety)
· Database validation (UAT) and Go-Live
· User account management
· Agree key risk indicators for risk-based and centralised monitoring

STEP 3

EXTERNAL DATA & SYSTEMS
· Data transfer specifications (labs, ePRO)
· Coding setup, dictionary versioning
· IXRS systems

CONDUCT OVERVIEW

STEP 4

DATA CLEANING
· Study and protocol specific training
· Data entry and QC
· Data validation
· Query management
· Protocol amendments
· Database revisions
· Data coding (WHODrug and MedDRA)
· SAE Reconciliation

STEP 5

TRACKING & REPORTING
· Patient cleaning, planning and tracking
· Management of protocol deviations
· Provision of DM status to client
· Provision of listings for medical or DSMB review
· Management of data review meetings

STEP 6

EXTERNAL DATA MANAGEMENT
· Test data loading
· Production data load
· External data reconciliation
· SDTM export

STUDY CLOSE-OUT OVERVIEW

STEP 7

DATABASE FINALISATION
· Final database cleaning
· Data review meeting
· External data finalisation
· Completion of all activities documented in database lock checklist
· Lock database
· Preparation of patient profiles
· Export of raw data to SDTM datasets

STEP 8

ARCHIVING
· Removal of all access to database
· Archive of database
· Provision of their data including searchable audit trails to all investigational sites
· Provision of datasets to statistics and sponsor
· Archiving of all documentation
· Quality check of data management compo -nents of trial master file

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CASE STUDY:
FULL SERVICE

TOP 5
PHARMA COMPANY
Assuring Client Study Continuity

CHALLENGE
· Client worked with a CRO that planned to stop full-service data management
· Client requested a regulatory compliant solution for ongoing study

SOLUTION OFFERED
· Developed project plan with clear data validation steps to transfer data to our inhouse Vitessa tool (including metadata and searchable audit trails)
· Prepared mapping programs to newly built database
· Test transfer and resolution of several mapping issues
· Transfer of all current data to Vitessa tool over one weekend

BUSINESS IMPACT
· Vitessa database went live on the Monday and active sites trained so that study could continue without time gaps

For further information, please contact our sales team : **contact@excelya.com**