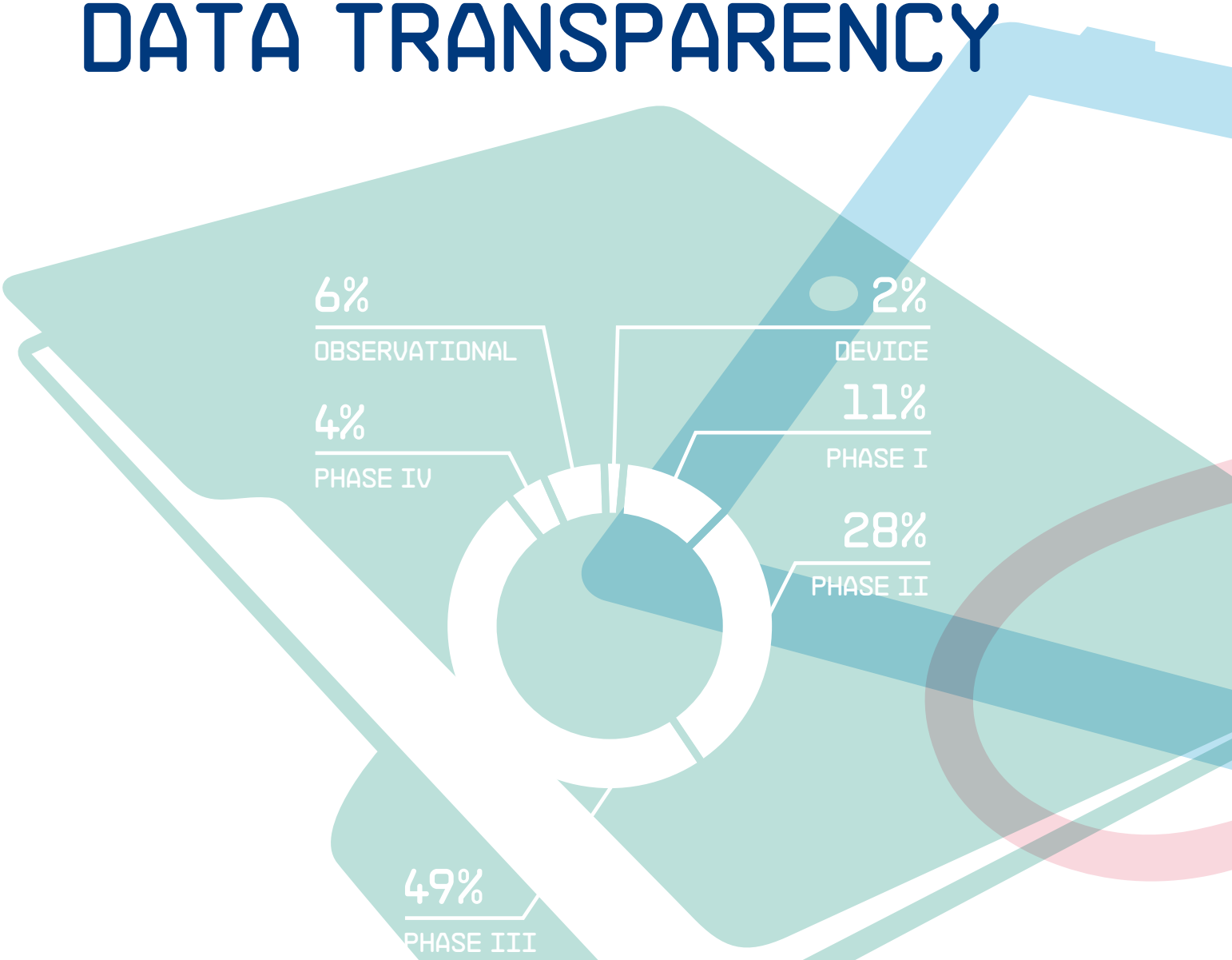
KCR DATA MANAGEMENT: DESIGNED FOR FULL DATA TRANSPARENCY



The quality of study data relies first and foremost on the quality of the tool used to collect the data. If the data points specified in the protol are not accurately collected, a meaningful analysis of the study's outcome will not be possible. Therefore, the design, development, and quality assurance processes of a CRF must receive the utmost attention.

— Good Clinical Data Management Practice, April 2011

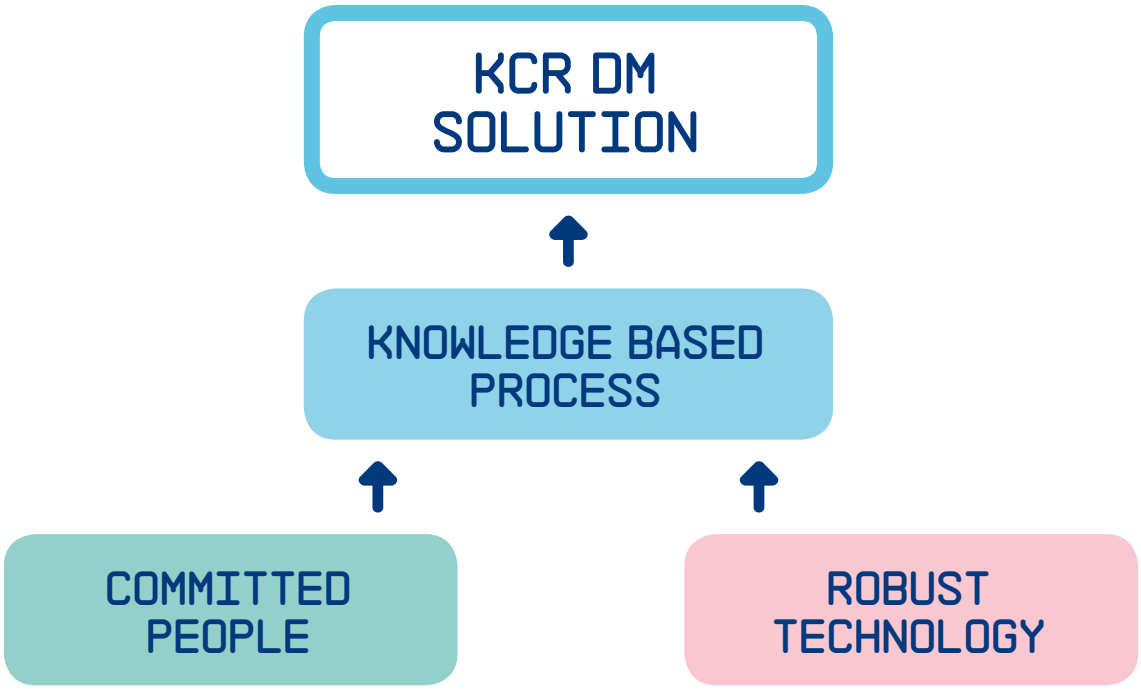
KNOWLEDGE / COMMITMENT / RESULTS

KCR

KCR KNOWS THAT ACCURATE CLINICAL TRIAL DATA IS THE LIFELINE OF CLINICAL STUDIES

KCR DELIVERS ALL THE SUPPORT AND TOOLS TO ITS CLIENTS THAT ARE NECESSARY TO MAKE THE CORRECT DECISIONS

As an expert provider of a wide spectrum of clinical development support services, KCR has developed a supreme Data Management (DM) solution geared towards full data transparency as well as delivering the highest level of quality within the defined timelines and in adherence to study budgets, all the while ensuring the meeting of all Good Clinical Practice (GCP) and ICH requirements.



KCR DM SOLUTION IS BASED ON A KNOWLEDGE-BASED PROCESS BORNE BY A COMMITTED TEAM OF EXPERT PEOPLE AND A PROVEN, SECURE AND RELIABLE TECHNOLOGY DESIGNED FOR FULL DATA TRANSPARENCY.

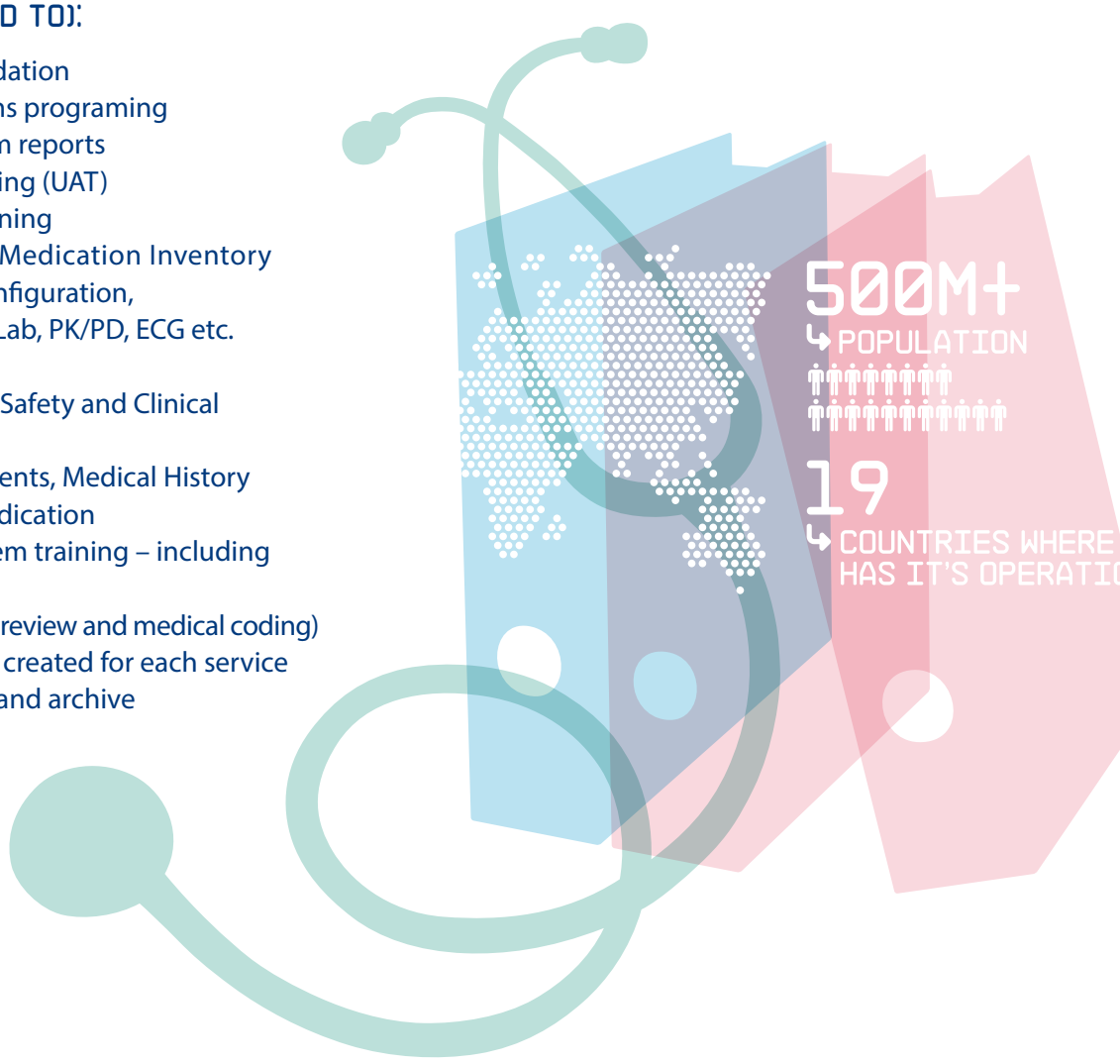
KNOWLEDGE-BASED: PROCESSES@KCR DM

KCR's DM is guided by impeccable data management processes providing the know-how necessary to perform all activities throughout the lifecycle of a study to the highest quality possible. Our Standard Operating Procedures (SOPs) enable a clear audit trail for each process phase depending on stage of the study as well as a full index of documentation required of audits, inspections or for submission purposes.

KCR CONSTANTLY SURVEILS ITS DATA MANAGEMENT PROCESSES BY APPLYING A FULLY TRANSPARENT AND HIGHLY EFFECTIVE QUALITY ASSURANCE (QA) PROCESS.

KCR'S FULL PACKAGE OF DM SERVICES INCLUDES (BUT IS NOT LIMITED TO):

- eCRF design and validation
- Automated validations programing
- Programing of custom reports
- User Acceptance Testing (UAT)
- Continuous data cleaning
- Randomization and Medication Inventory /Drug Supply tool configuration,
- External data set up, Lab, PK/PD, ECG etc. data imports
- SAE Reconciliation of Safety and Clinical database
- Coding of Adverse Events, Medical History and Concomitant Medication
- Study team EDC system training – including e-learnings
- Database QC (for data review and medical coding)
- Listing of documents created for each service
- Database Lock (DBL) and archive



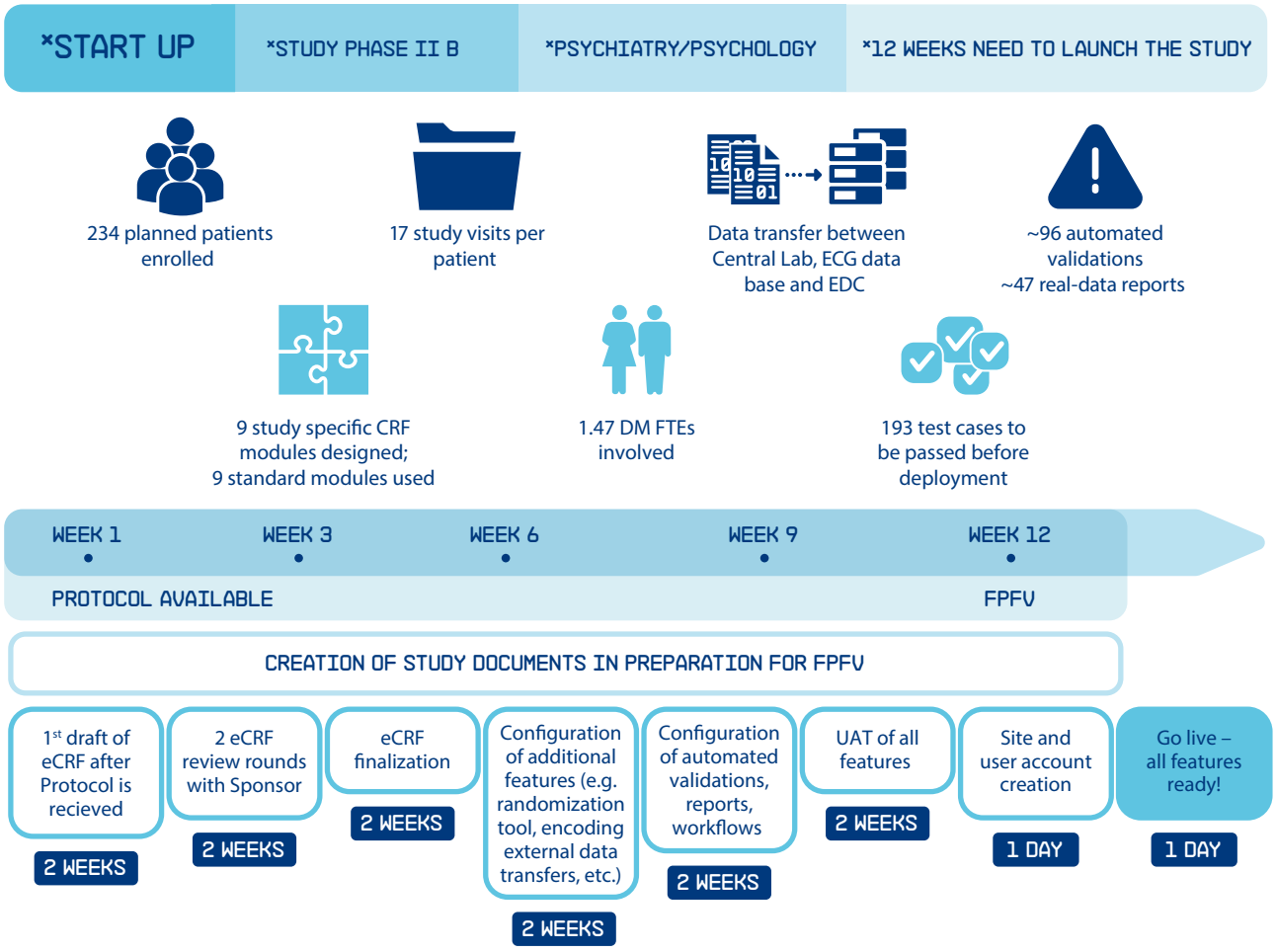
ALL DM SERVICES OFFERED BY KCR ARE IN STRICT ALIGNMENT WITH OUR OPERATING FRAMEWORK AND STRUCTURED AROUND THE THREE MAIN PHASES OF THE CLINICAL TRIAL: START-UP, CONDUCT, AND CLOSE-OUT.

➜ START-UP PROCESSES

Start-up processes at KCR are designed to set up the Electronic Data Capture (EDC) tool within a maximum of 12 weeks and to include the performance of two client eCRF review cycles as well as thorough User Acceptance Testing (UAT). Such a competitive timeline is made possible by utilizing pre-validated libraries of modules/forms, automated validations and reports. The processes ensure the EDC is available (with all features implemented) for First Patient First Visit (FPFV) to guarantee continued data entry from day one of the study.

CASE STUDY I: START-UP PROCESS WITH A 12 WEEKS LAUNCH PERIOD

(PHASE IIB PSYCHIATRY/PSYCHOLOGY STUDY)



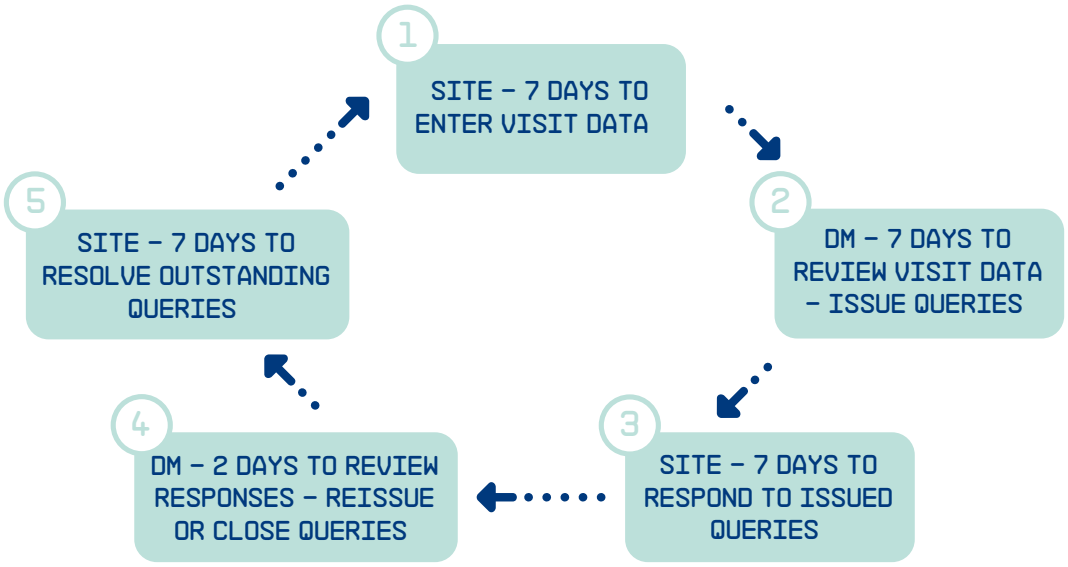
➜ CONDUCT PROCESSES

HIGH QUALITY DATA WITH TIMELY DELIVERY IS CRUCIAL, GIVEN THE COMPETITIVENESS OF THE DRUG DEVELOPMENT ENVIRONMENT AND THE METICULOUS FOCUS ON CYCLE TIMELINES.

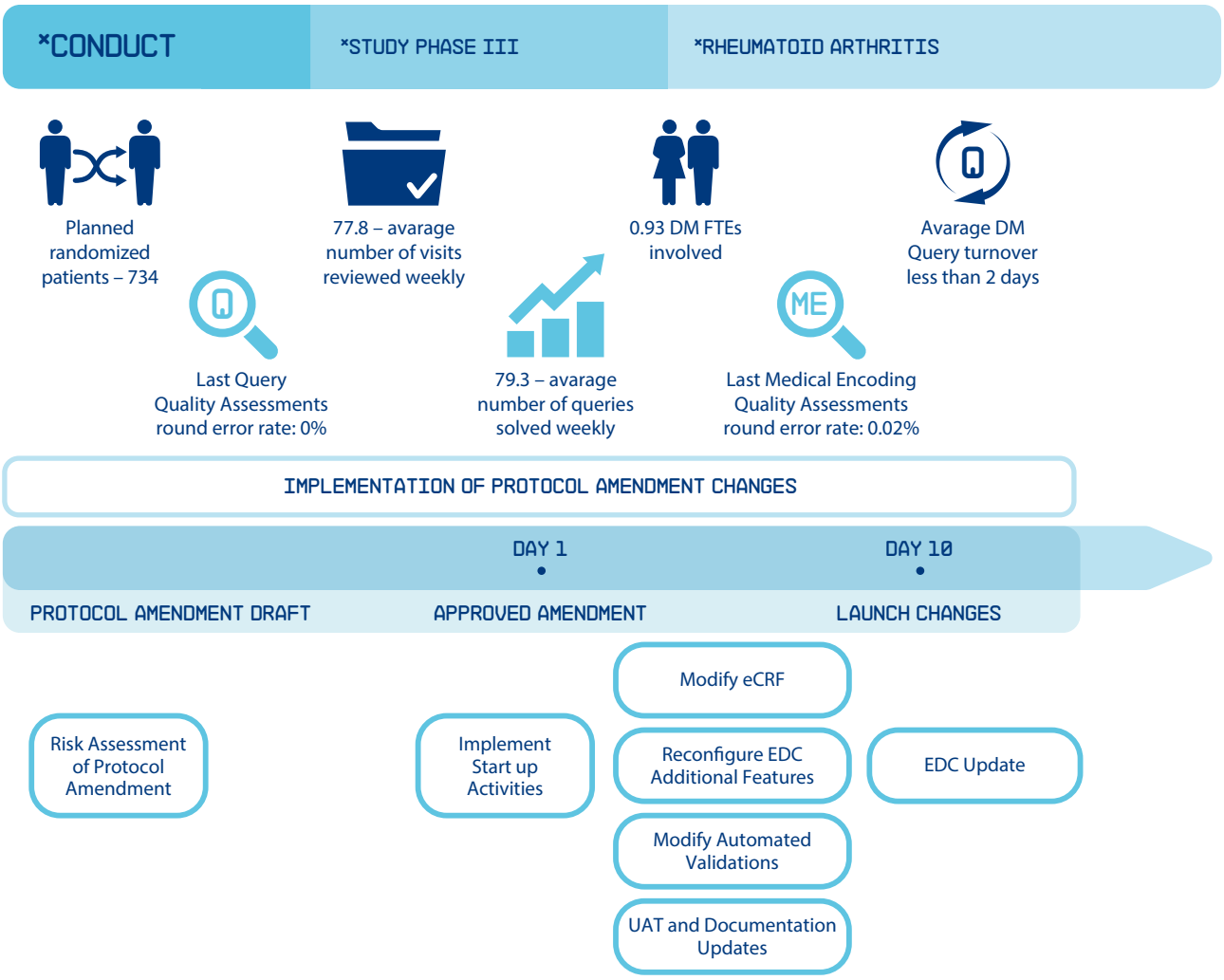
The conduct processes at KCR ensure accurate prediction, prevention and dependable reaction on the data collected within a timely manner.

Our experienced Data Management Protocol Leads meticulously control the data flow by help of statistical analysis tools and implemented risk based monitoring approach methods to ensure the highest quality of the data collected.

KCR's Data Management ensures an ongoing data review within predefined timelines:



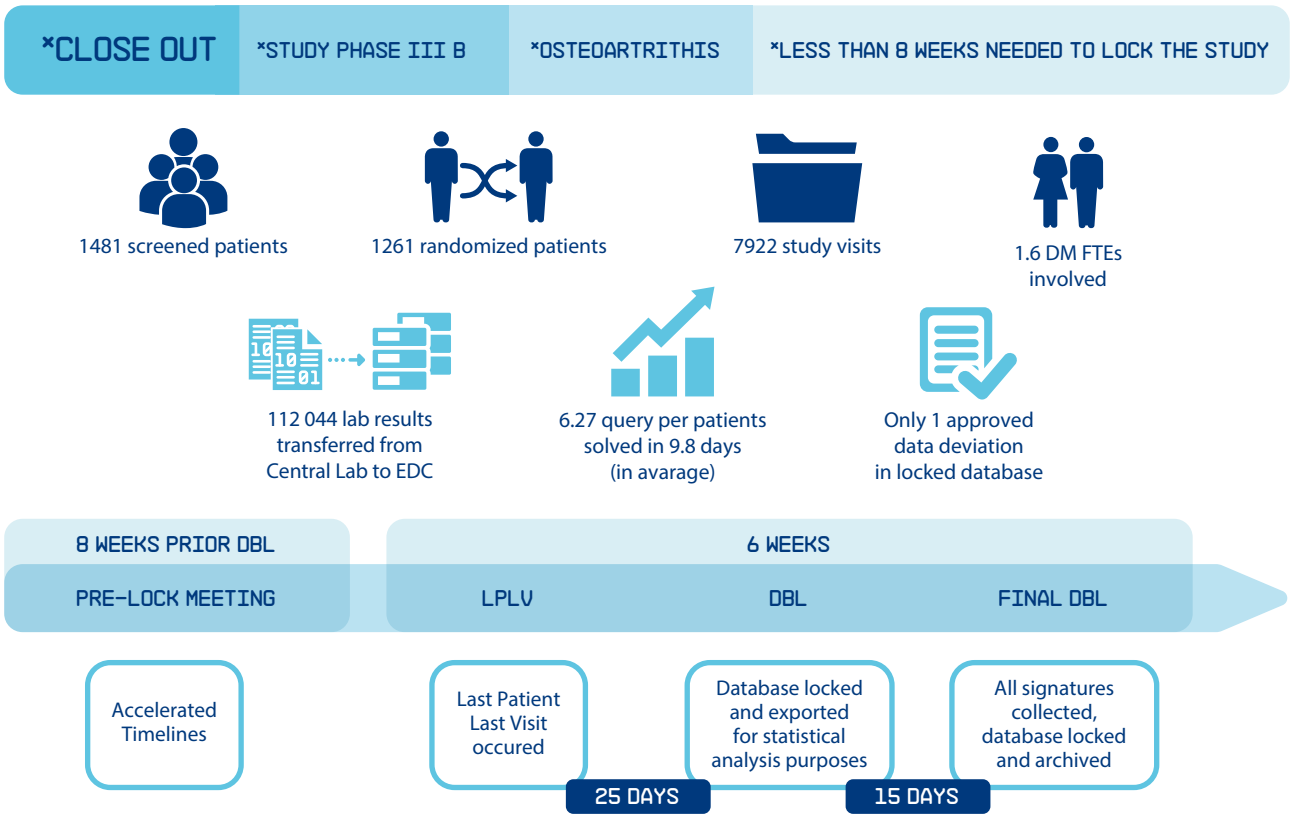
CASE STUDY II: CONTINUOUS DATA HANDLING (PHASE III RHEUMATOID ARTHRITIS STUDY)



➜ CLOSE-OUT PROCESSES

KCR's close-out processes are designed to maximize efficiency of Database Lock (DBL) activities and to ensure all DBL milestones are met. Our multi-step process facilitates a database lock within ~8 weeks from Last Patient Last Visit (LPLV) to final DBL without any need to unlock it at a later stage because of critical findings.

CASE STUDY III: DATA LOCKED IN LESS THAN 8 WEEKS (PHASE IIIB OSTEOARTHRITIS STUDY)



↳ COMMITTED: PEOPLE@KCR

KCR DM TEAM COMPRISES EXPERIENCED AND RELIABLE EXPERTS WITH A CLEAR SPLIT OF RESPONSIBILITIES. EVERY PROJECT HAS A DESIGNATED DATA MANAGEMENT PROTOCOL LEAD WHO ENSURES THAT STUDY NEEDS ARE MET AT ALL TIMES.

KCR's international team consists of professionals with an average of six years' field experience and a range of expertise and background in:

- PROJECT MANAGEMENT
- REMOTE MONITORING
- TRAINING
- CENTRALIZED MONITORING
- QUALITY ASSURANCE
- RISK ASSESSMENT

At KCR successful people never stop learning: we put significant emphasis on continuous and thorough training of our staff to ensure the delivery of highest quality services.

"ALWAYS THINK BIG"

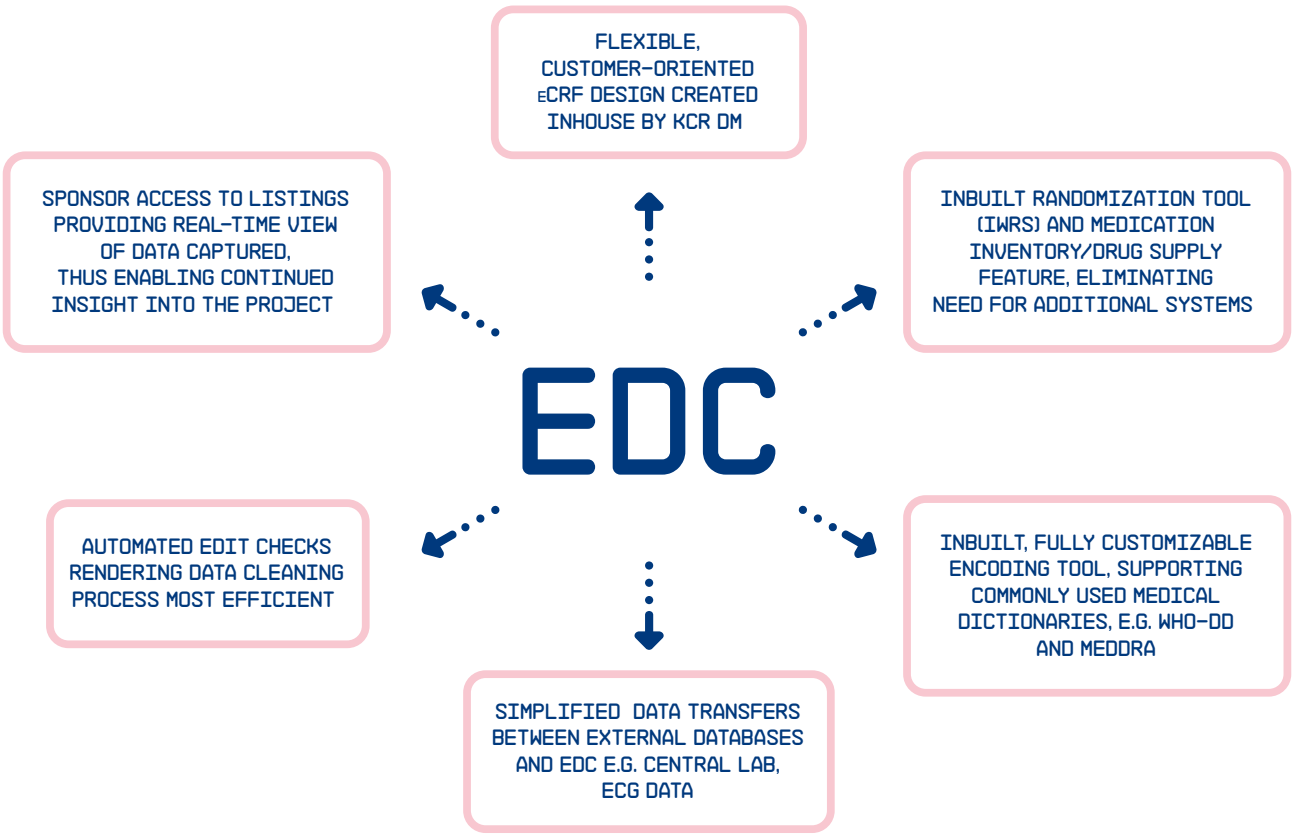
We are convinced that innovations are the cornerstone for success, each member of our staff shares a similar mind-set and vision working towards the best results. Our DM team is personally liable for all actions and results, and follows one of our core values in all day-to-day activities.

"IF IT'S TO BE, IT'S UP TO ME"

ROBUST: TECHNOLOGY@KCR

KCR TRAINED IN-HOUSE EXPERTS TAKE ADVANTAGE OF ALL POSSIBLE CAPABILITIES OF THE TOOL TO DELIVER A CUSTOMIZED AND TRANSPARENT SOLUTION TO EACH CLIENT.

KCR uses **Clincase**, a secure, flexible and reliable EDC solution delivered by Quadratek and utilized by leading pharmaceutical companies across the globe.



All technology used by KCR Data Management is compliant with 21CFR Part 11 and all other industry standards including CDISC ODM and CDASH.

KCR: EXCELLENCE IN CLINICAL TRIALS SINCE 1997

KCR is a Contract Research Organization (CRO) with a dynamic team of over 300 professionals operating across 19 countries in Europe as well as the U.S. With 18 years of experience, almost 400 trials executed, 35,000 patients recruited and over 3,000 sites contracted, KCR is a strategic solutions provider and a reliable alternative to top tier CROs, delivering the all-important flexibility.

We provide services on long standing contracts to 12 out of the Top 20 Global Pharma companies, as well as biotech firms from Europe, Israel, and the U.S.

KCR offers full service capabilities via three types of professional product lines:

- Trial Execution
- Functional Service Provision (FSP)
- Late Phase

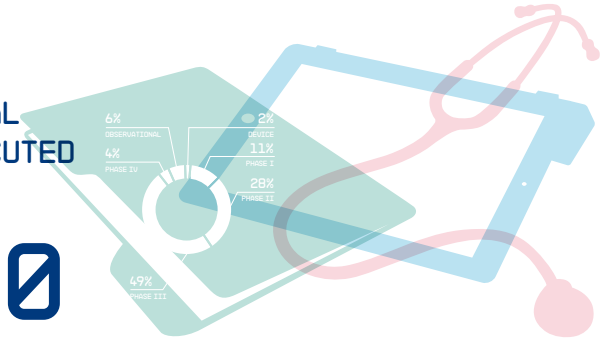
KCR: WE SEE HUMAN BEHIND EVERY NUMBER.

18

18 YEARS OF EXPERIENCE

400

400 CLINICAL TRIALS EXECUTED

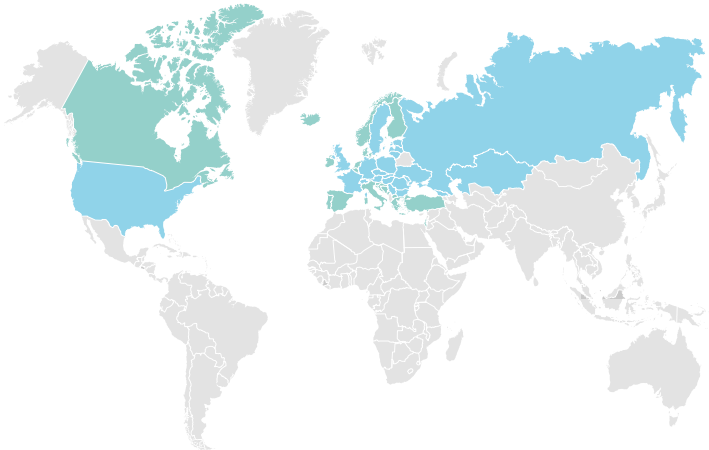


3,000

ALMOST 3,000 SITES CONTRACTED

30,000

OVER 30,000 PATIENTS RECRUITED



KCR Offices
Strategic Alliance

KNOWLEDGE / COMMITMENT / RESULTS

KCR

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