

# REAL WORLD EVIDENCE

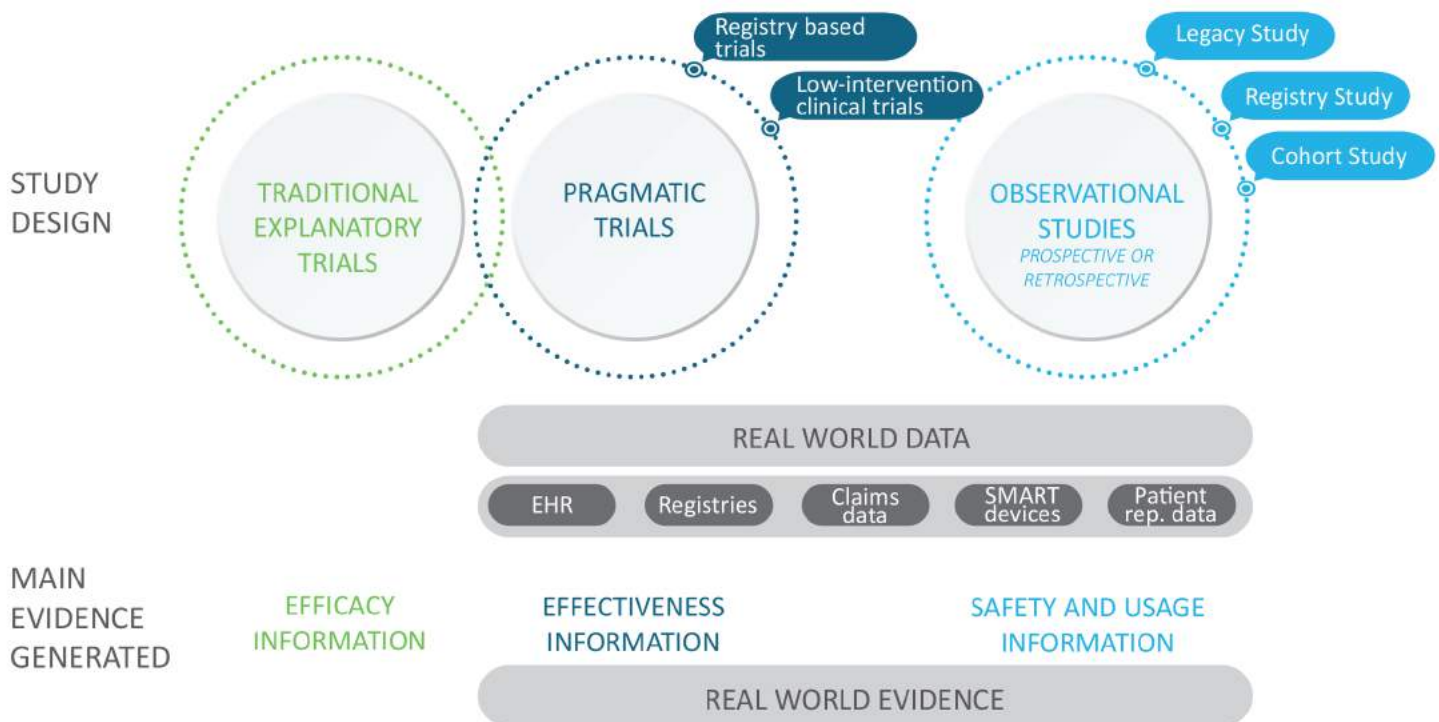
## ACCESS TO DATA IS JUST THE START



Real World Evidence (RWE) is essential to determine the benefit/risk balance of treatments in routine clinical practice across populations and geographic regions. In this way, it helps to improve patient outcomes. As our experience grows, so do the opportunities we see to extend the use of Real World Data (RWD) to answer both safety and effectiveness questions and not only in observational studies, but also in randomised trial settings (pragmatic trials). But the question is how to transform RWD into a key source of evidence in a drug development programme? Besides ensuring the best data for a particular study, turning RWD into RWE involves having a thorough understanding of the methodology and the data science required.

“ From methodology to operations and from the emerging field of pragmatic trials to established use in observational studies, Julius Clinical, the science CRO, can help you turn RWD into RWE. ”

### JULIUS CLINICAL: YOUR PARTNER FOR EVIDENCE GENERATION ACROSS THE WHOLE DRUG DEVELOPMENT CYCLE



### QUESTIONS OUR PARTNERS ASK US FREQUENTLY

- When does RWE add value to a drug development programme?
- What do you need to consider before going ahead with an RWE study?
- When does a pragmatic trial have advantages over an observational study?



WE HELP YOU UNDERSTAND THE CHALLENGES AND FIND SOLUTIONS, BY IDENTIFYING OPPORTUNITIES TO INCORPORATE RWE INTO INNOVATIVE STUDY DESIGNS.

## OUR EXPERIENCE, YOUR BENEFIT



### METHODOLOGICAL EXPERTISE

Our RWE specialists are members of the IMI GetReal Initiative and have ample experience with RWE studies, including pragmatic trials.



### IN-DEPTH KNOW-HOW ABOUT RWD SOURCES AND DATA SCIENCE

Our data scientists are part of the IMI BigData@Heart programme to deliver scalable RWE insights for drug development and personalised medicine.



### PROTOCOLS AND TRIAL DESIGNS

We are involved in the IMI Trials@Home project and are experts in risk-based monitoring, which is especially important in relation to pragmatic trials.



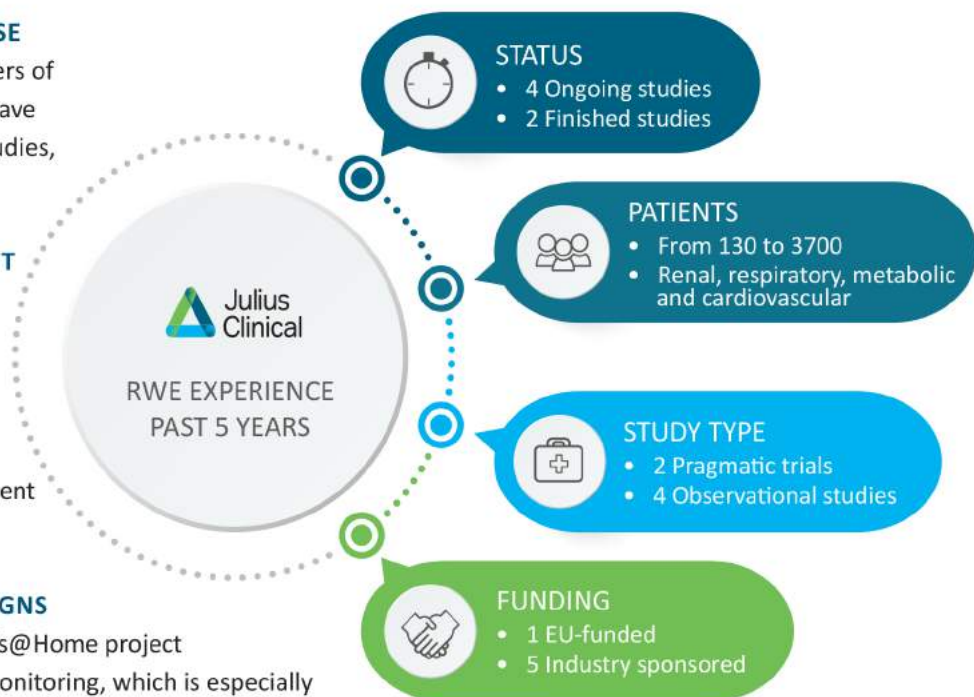
### OPERATIONAL EXCELLENCE

Julius Clinical is a scientific leader in randomised clinical trials, with thorough knowledge of the full Phase I – IV development spectrum.



### AGILE ORGANISATION

We react quickly to study requirements as well as to the changing RWE landscape and adapt processes to optimise study outcomes.



## COLLABORATING WITH THE EXPERTS



**Diederick E. Grobbee, MD, PhD**  
Chief Scientific Officer at Julius Clinical and Professor of Clinical Epidemiology at the University Medical Center Utrecht, the Netherlands.



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Professor of Pharmaco-epidemiology at the University Medical Center Utrecht, the Netherlands.