pulse infoframe™

Drug Development Journey

Supporting the patient journey through real world data (RWD)

We help communities around the world collect and share data and lived experiences to provide real world evidence (RWE) to advance and accelerate the development of effective treatments.

STEP 01 Drug Discovery

Do we understand the genetic cause and disease pathway to inform our drug discovery?

Our platform healthie™ 2.0 leverages structured RWD through natural history studies to support drug discovery by:

- proving the genetic cause of a disease
- finding the underlying disease pathway
- defining the disease molecule
- influencing research areas and providing input for priorities

STEP 02 Pre-clinical Research

Will the molecular target influence the disease?

RWE can help to define the characteristics of desired drug molecules and optimize lead candidates. Utilizing our platform healthie™ 2.0 to collect early RWD can:

- support and strengthen regulatory filings
- prove that the molecular target influences the disease in animal models
- identify potential compounds
- ensure compound can be manufactured at scale
- collate documents for filing

STEP 03 Clinical Trial Design

Do we understand the burden of the clinical trial on our participants?

Clinical trials are a vital stage in drug development. However, their success depends on people-centered trial design. Partnering with patient groups to collect RWD healthie™ 2.0 can help with:

- protocol review
- patient recruitment
- trial design
- developing clinical endpoints in clinical research

STEP 04 Trial Phases I II III IV

Is this a safe and effective therapy?

Data collection during phases I, II, and III (pre-approval and IV (post-approval) is needed to evidence findings during clinical research. Gathering sufficient evidence in small populations can be challenging. RWD collected in healthie™ 2.0 can:

- serve as a comparator arm for studies
- evaluate safety and efficacy
- support pricing and reimbursement

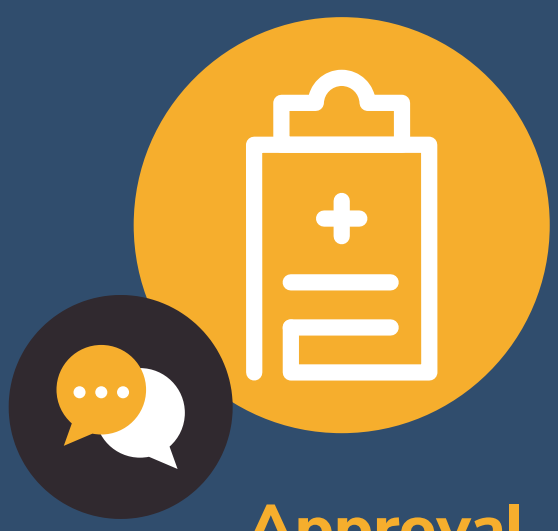
STEP 05 Analysis & Dissemination

How can we leverage the RWE we create?

Drug development is a long process, by sharing your RWE you can:

- support regulatory filings
- support publications
- engage KOL's and patient communities
- compare data against real-world impact

STEP 06 Approval & Reimbursement



How can RWE support market authorization?

healthie™ 2.02.0 provides structured data mapped to OMOP* and can be read into CDISC* and mCODE*, standards required by the regulatory bodies the FDA (US) and EMA (EU). Data collected to industry standards will:

- aid regulatory approvals with high-quality data
- strengthen reimbursement negotiations
- future proof your data

Partnering for the journey ahead: Together We Achieve More:

*Observational Medical Outcomes Partnership (OMOP) - Clinical Data Interchange Standards Consortium (CDISC) - minimal common oncology data elements (mCODE))

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