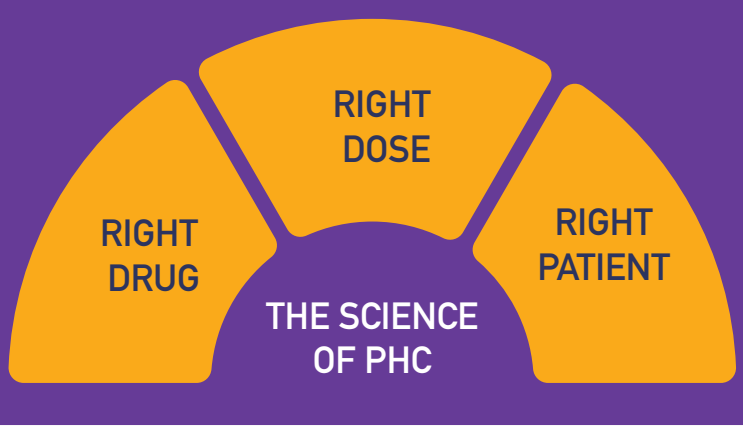
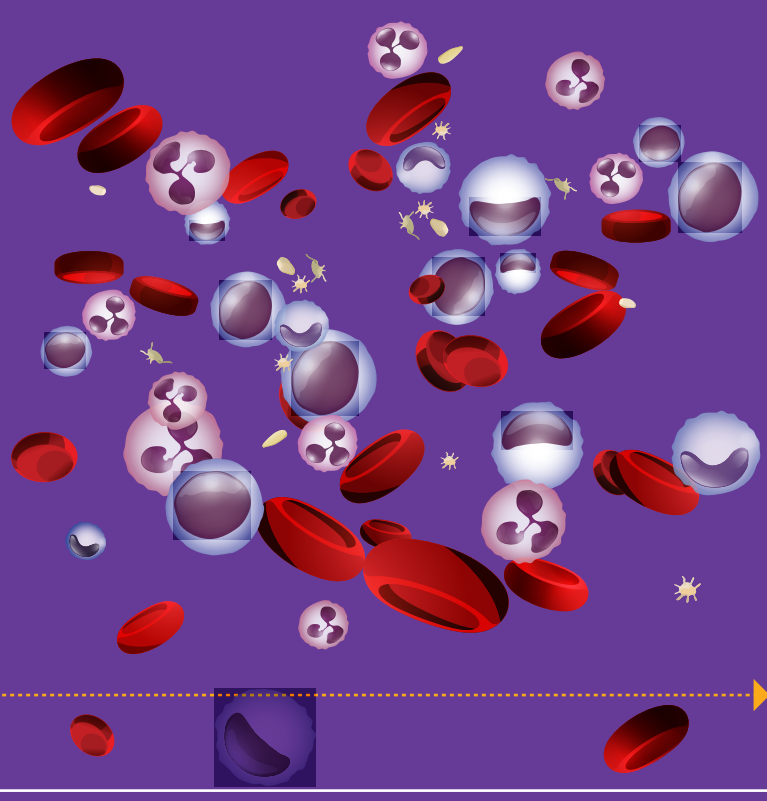


DEVELOPMENT SCIENCES

MRD

LEARN MORE ABOUT MRD AND FIND OUT HOW THE SCIENTISTS IN DEVSCI ARE USING IT TO BRING MEDICINES TO PATIENTS FASTER.



the science

WHAT IS IT?

Minimal residual disease (MRD) is the presence of a very small amount of cancer cells that remain after treatment.

The efficacy of treatments for blood cancer is often measured by how completely the cancer is removed from the body. Recent advances in technology have made it possible to detect traces of cancer - called minimal residual disease (MRD).

Identifying the presence or absence of residual blood cancer (i.e. MRD-positivity or -negativity) may provide a gauge of the extent of a person's response to treatment, as well as identify patients at high risk of relapse.

With growing evidence of on the clinical relevance of MRD as a measure of efficacy, regulatory authorities are considering MRD status in diseases as a potential surrogate for endpoints like progressive-free survival or overall survival.

our work

A FEW HIGHLIGHTS OF OUR SCIENTIST'S WORK ON MRD:
ENABLING EARLY READ OUTS, FASTER ACCESS AND DIFFERENTIATION FROM COMPETITION

2004: INITIAL ADOPTION

Early adoption of MRD assessments in Roche/GNE clinical trials in CLL identified MRD as an independent prognostic factor for patients with CLL

EARLY 2018: DRIVING DIFFERENTIATION

An early success was the inclusion of MRD negativity rates into the VENCLEXTA label in relapsed/refractory CLL, and differentiating VENCLEXTA from competition, as a novel agent that induces deep and durable MRD negativity, which can be assessed via peripheral blood test. An expanded description of MRD was subsequently added to the frontline CLL label providing the building blocks to the future success of using MRD as a primary endpoint.

LATE 2018: COLLABORATION WITH THE FDA

Both FDA and industry leaders have used the VENCLEXTA Phase 3 MURANO study in CLL as an example of how adequate information was provided for the inclusion of MRD as a clinically relevant measure of efficacy in the drug label.

2019: MRD AS A PRIMARY ENDPOINT

FDA endorsed the use of MRD as a primary endpoint in a Phase 3 registrational VENCLEXTA trial, instead of progression-free survival, resulting in a smaller and faster trial design and accelerating study readout. These efforts advance our mission to bring novel treatments to patients faster and drive innovation in drug development.

> THE INCLUSION OF MRD IN THE VENCLEXTA LABEL AND FDA'S ENDORSEMENT OF MRD AS A PRIMARY ENDPOINT IS PRECEDENT-SETTING BOTH AT ROCHE AND FOR THE INDUSTRY AND ADVANCES OUR COMMITMENT TO BRING NEW TREATMENTS TO PATIENTS FASTER.
>
> -Elizabeth Punnoose, Sr. Scientist, OBD

IMPACT TO THE PIPELINE

By using MRD as the primary endpoint, we will be able to accelerate our launch timeline by 15 months.

the future

Our work advances new use cases for MRD in hematological malignancies and solid including identification of high-risk patients with residual disease for early intervention studies and for use as a surrogate endpoint.

more info

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HISTORY & EVOLUTION OF MRD
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Development Sciences