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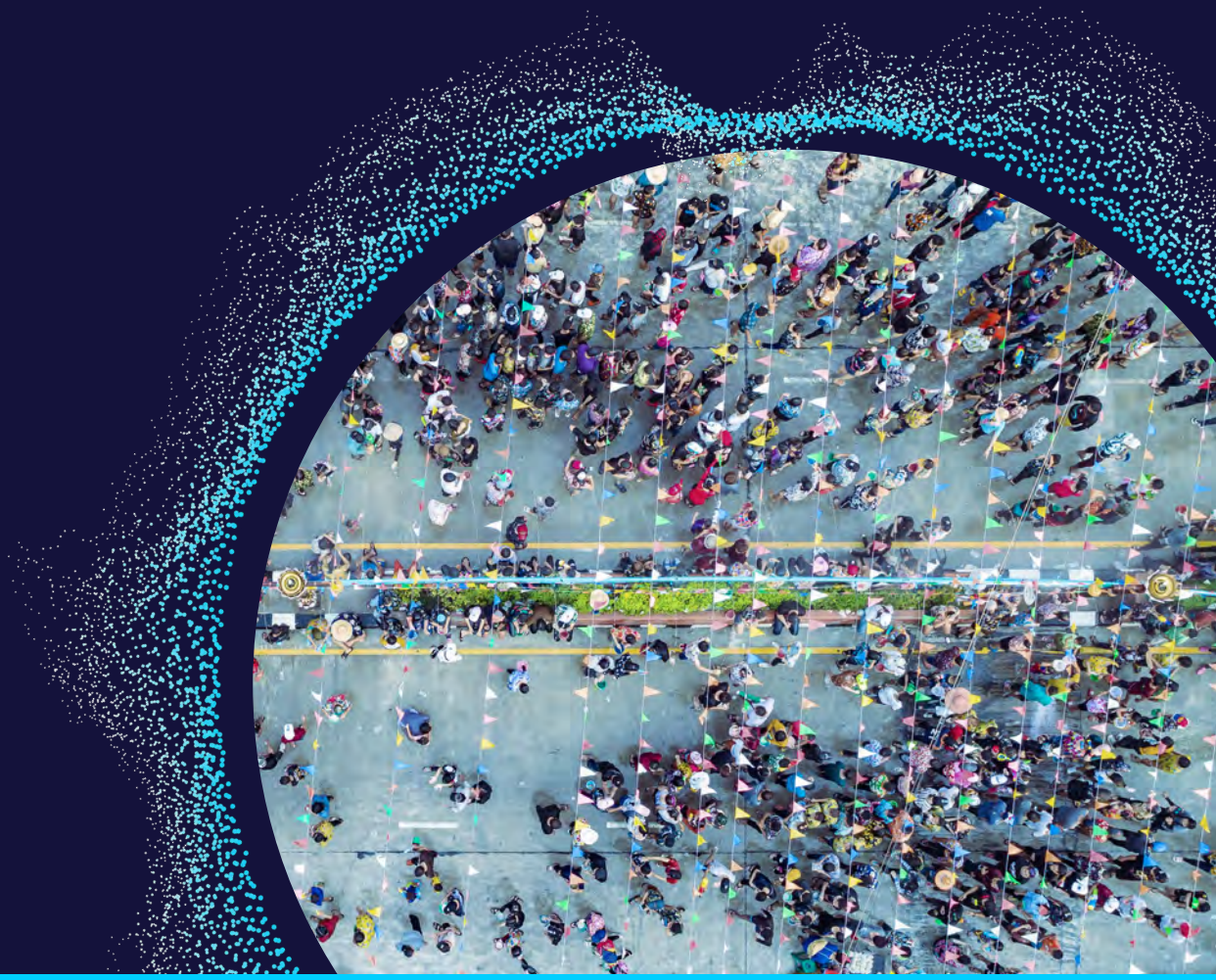
CLINICAL

Use Case

Citeline Real-World Data Protocol Design and Patient Population Impact

Learn how Citeline's Real-World Data (RWD) can help you understand the impact of your protocol design on the volumes of potential patients that can be enrolled



Situation

Before finalizing their clinical trial protocol, a client wanted to analyze three iterations of eligibility criteria. They had several goals in mind:

- Ensure they weren't looking for a 'needle in a haystack' based on the eligibility criteria
- Confirm the ability to enroll diverse patient populations
- Shield from unnecessary or unintentional exclusion of patients

Solution

To identify the optimal protocol design, we analyzed each protocol in isolation, leveraging Citeline's gold-standard, harmonized data assets:

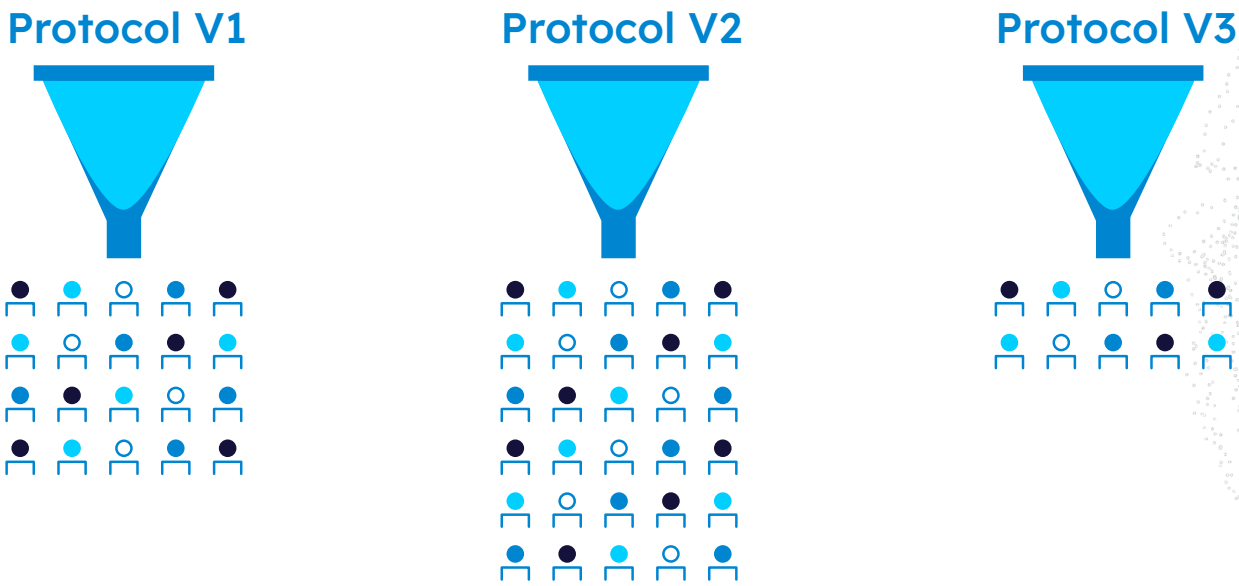
Real-world data
Leveraging medical claims and lab data, we manually reviewed both protocols by each line of the inclusion/exclusion criteria represented by an ICD-10 code

Trialtrove and Sitetrove
Overlaying Citeline's clinical trial and site data, we further refined trial design

Together, these data sources were used to:

- Obtain a real-world view of the number of protocol-matched patients each protocol produced
- Break down patient populations by race, gender, and age
- Identify limiting inclusion/exclusion criteria factors

RWD for Protocol Design and Patient Population Impact



Volume of Protocol-Matched Patients to Target for Recruitment

Value

In the end, leveraging Citeline's insights allowed our client to not only design a strong protocol with confidence, but also:

Design a clinical trial protocol that strikes the right balance between scientific rigor and operational feasibility

Avoid costly protocol amendments by confirming availability of potential participants based on inclusion/exclusion criteria in advance

Ensure the protocol design does not unintentionally exclude diverse populations and is as representative as possible

The Citeline Difference

Tap into unique combination of powerful, granular data sources to generate nuanced insights

Work with a **dedicated team of experts** with hundreds of years of combined clinical and commercial expertise, delivering insights how you need them

Utilize support throughout the R&D lifecycle – from initial strategy/ commercial analysis to clinical development and disclosure

Learn how Citeline's real-world data (RWD) can help you understand the impact that your protocol design has on volumes of eligible patients

LEARN MORE

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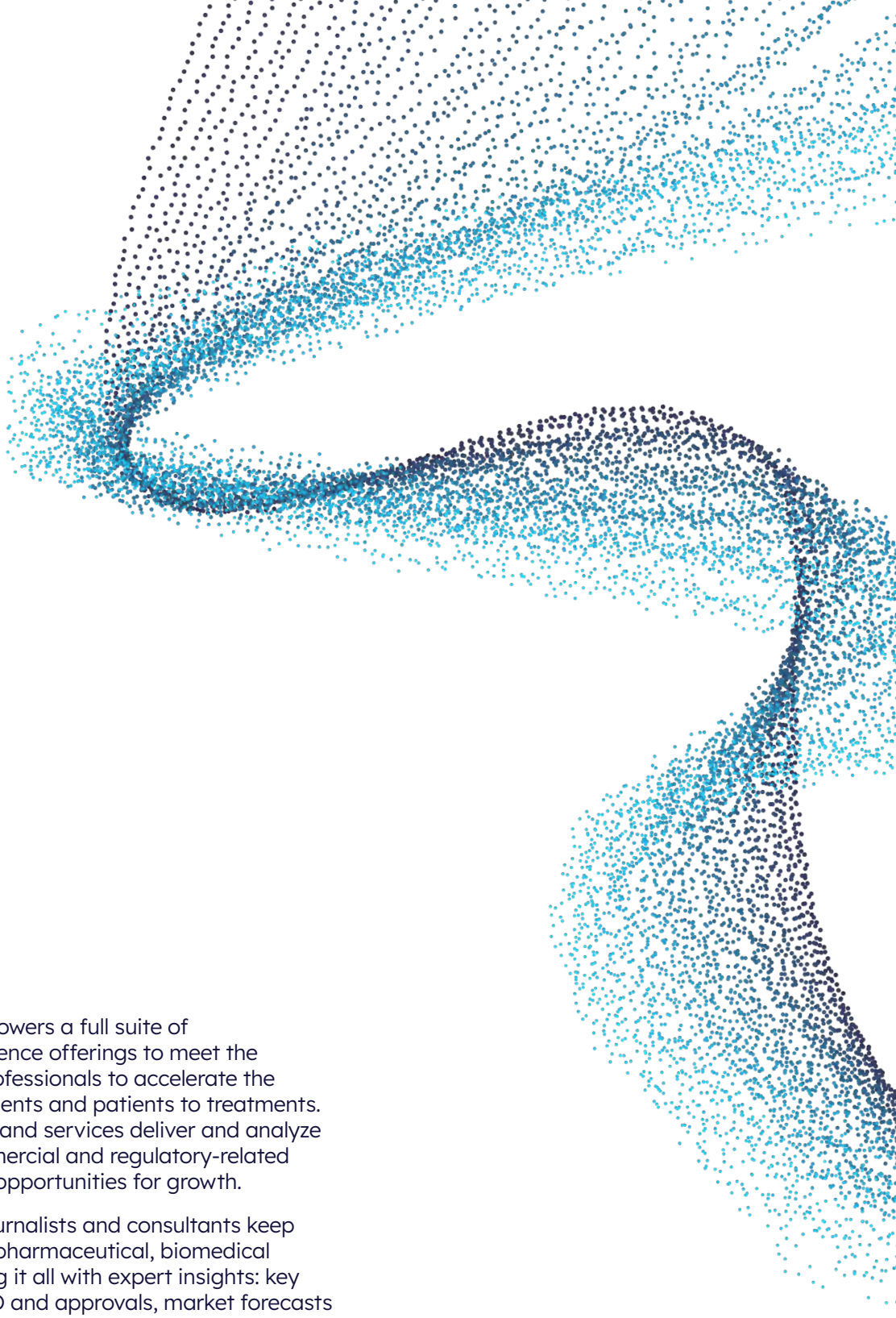

Citeline, a Norstella company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial and regulatory-related decisions and create real-world opportunities for growth.

Our global teams of analysts, journalists and consultants keep their fingers on the pulse of the pharmaceutical, biomedical and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts and more. For more information on one of the world's most trusted life science partners, visit Citeline.com