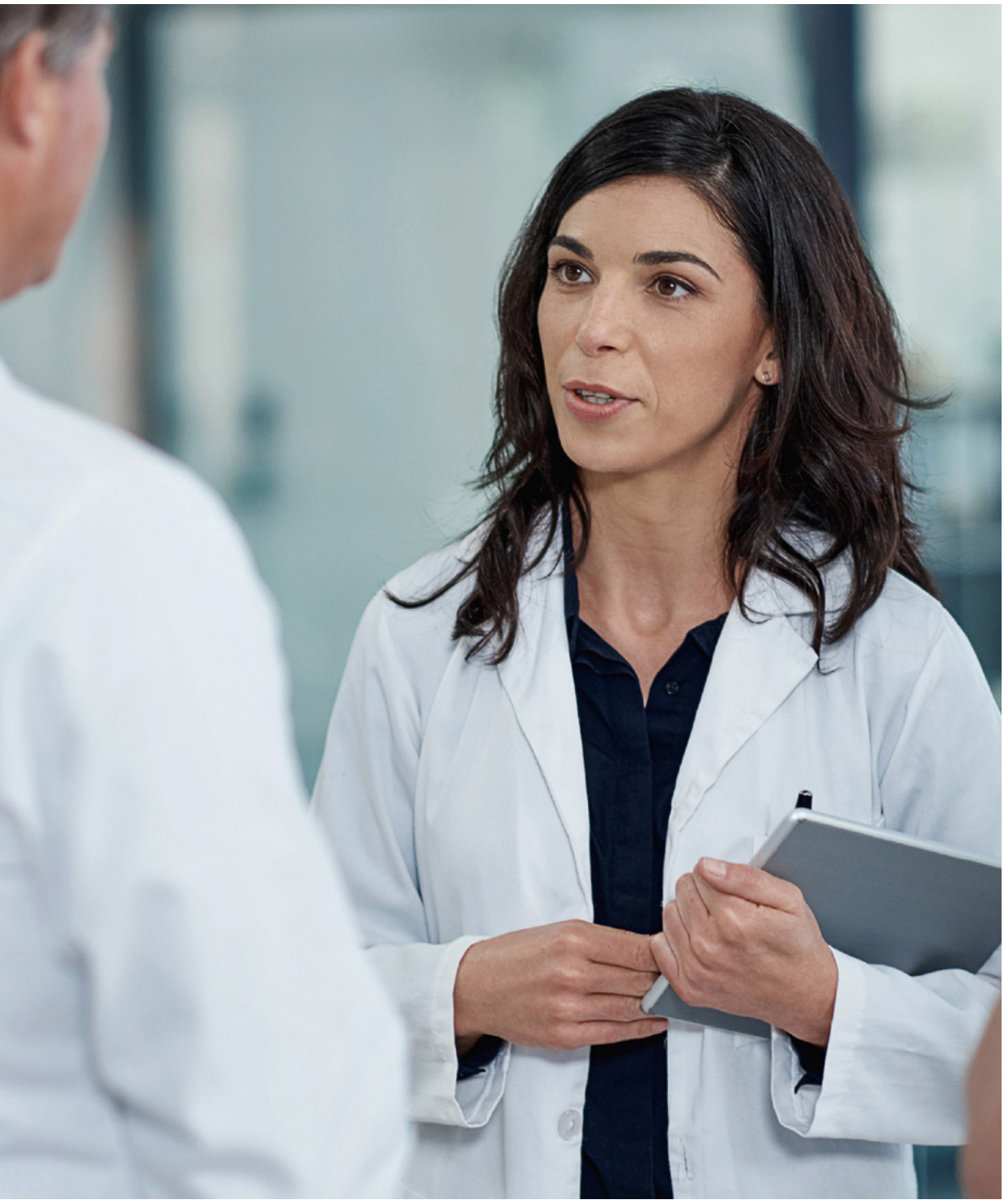
EMPIRIC



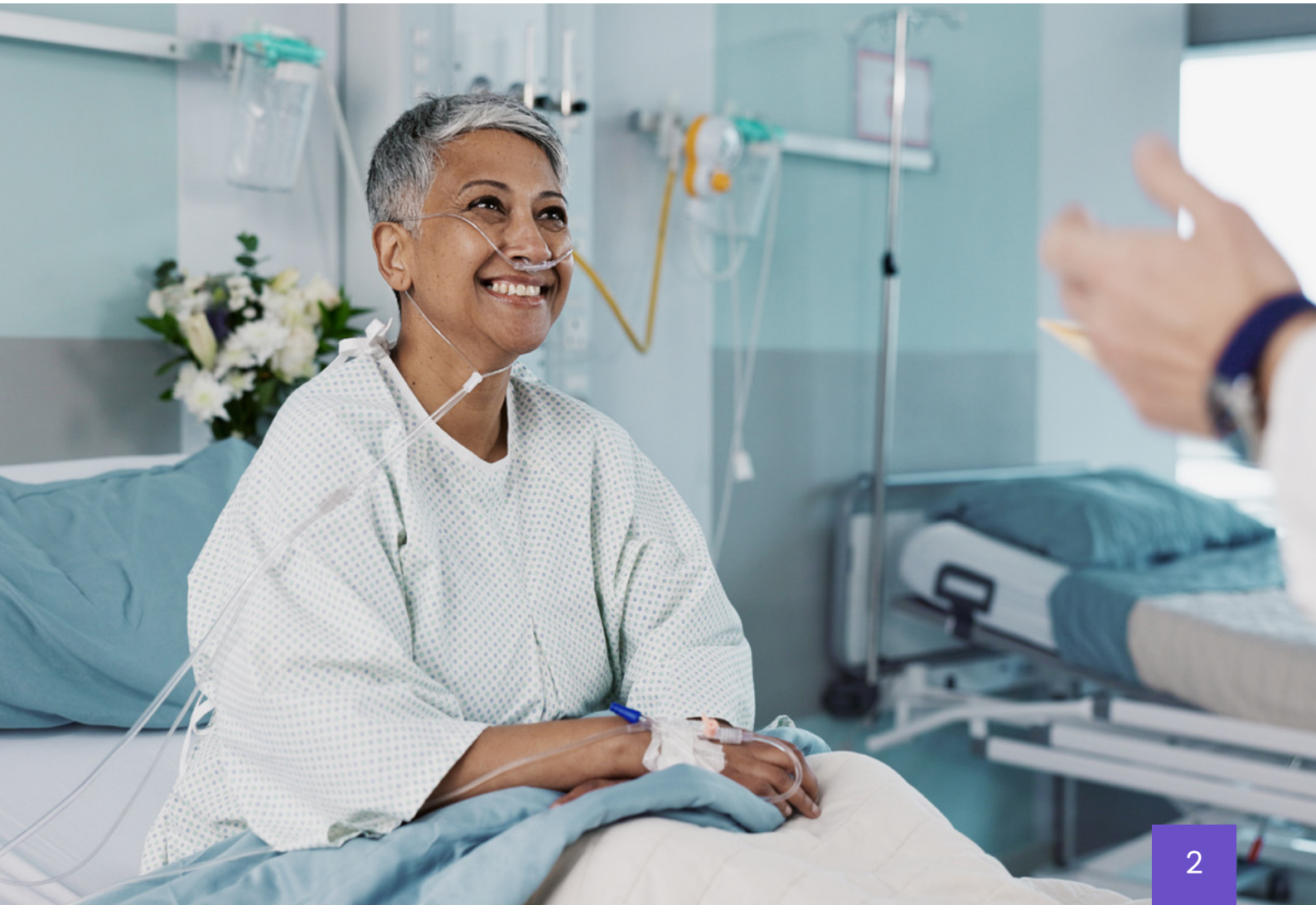
# 10x Smarter and Faster:

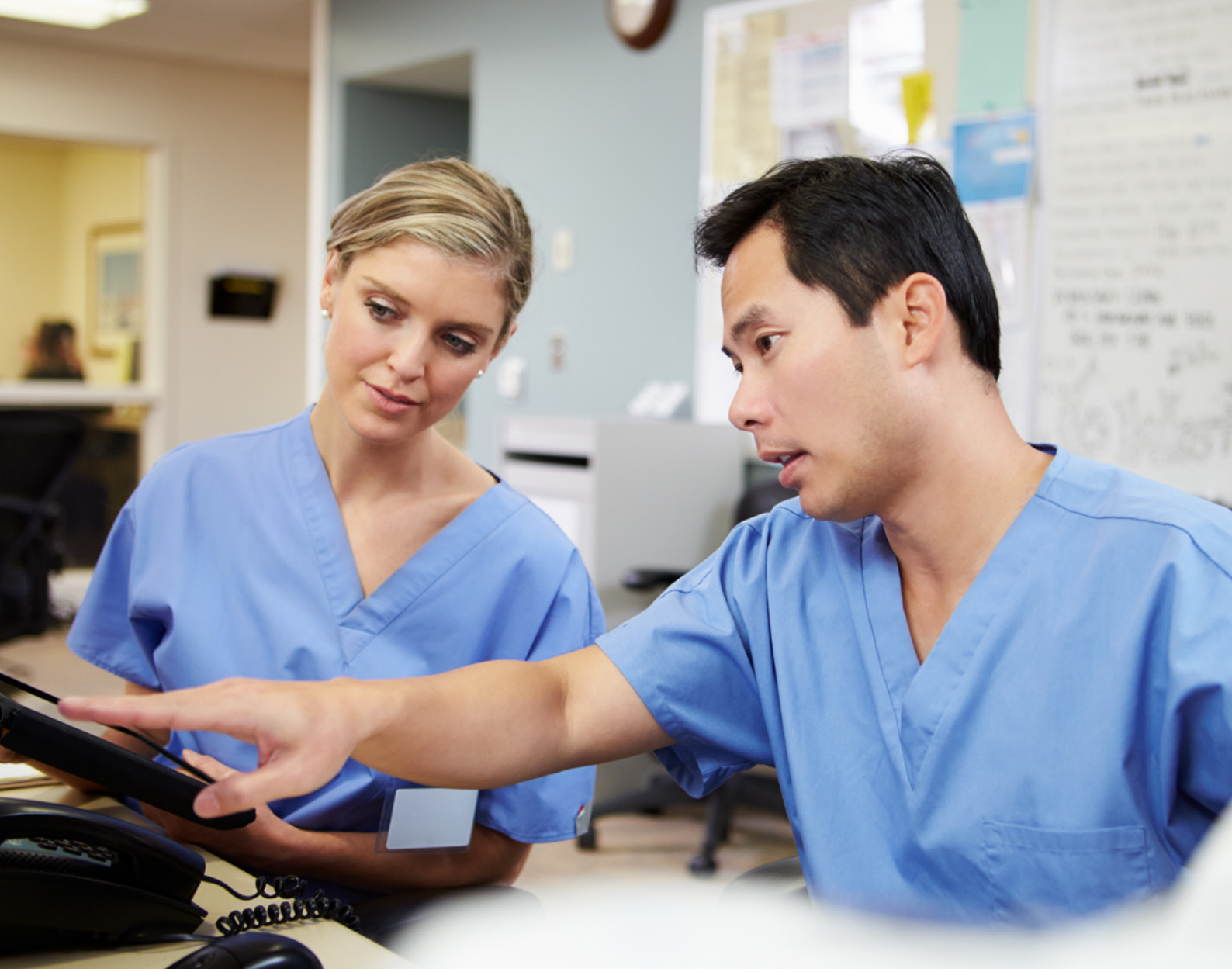
## Unlocking the Full Potential of Adaptive Platform Trials

# Executive Summary

Adaptive Platform Trials (APTs) have the potential to revolutionise clinical research by introducing unprecedented flexibility and efficiency. At Empiric, we believe this is just the beginning. Our vision for 2030 is to unlock the full potential of adaptive trials, achieving a 10x improvement in speed, intelligence, and impact. Through five transformative layers of innovation, we aim to redefine how clinical trials are conducted, delivering smarter and faster solutions for patients worldwide.

Our core strategy is built on a “make once, use many” philosophy. By leveraging shared infrastructure and reusable trial components, we accelerate timelines, reduce costs, and create scalable solutions. This operational efficiency is the foundation for achieving our ambitious 10x vision.





# Introduction

Clinical trials are the backbone of medical innovation, yet they remain slow, costly, and fragmented. Adaptive trials introduced a new level of flexibility by enabling pre-specified design adjustments based on accumulating data. Adaptive Platform Trials (APTs) have further evolved this concept, creating shared infrastructure to test multiple interventions simultaneously.

Empiric's vision for 2030 pushes these innovations even further. By adopting a scalable, "factory model" for clinical trials, we aim to achieve a tenfold improvement in speed and intelligence. Our approach redefines clinical research by standardising processes, automating workflows, and embedding trials into healthcare systems.

# Revolutionising Clinical Trials: From Cottage Industry to Factory Model

Imagine a world where clinical trials are no longer slow, costly, and pieced together. At Empiric, we've unlocked a smarter, faster, and more cost-effective way to run trials by rethinking how they're structured. This isn't just evolution—it's a revolution.

Here's how it works: every trial ever conducted has two parts. Some elements are unique to the condition or treatment being tested, but many are common across all trials. What if you didn't have to reinvent the wheel every time? That's where the platform approach comes in.

Our platform is built on a "make once, use many" philosophy. We've designed a robust, reusable framework for the shared elements of trials — like protocol components, patient recruitment methods, data collection systems, governance approval, and contracts. These common elements are crafted once and then applied across every trial in the platform. Only the unique, bespoke aspects of each trial require customisation.

This streamlined structure creates dramatic efficiencies:

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|---|---|
| **Faster launches** | Trials no longer start from scratch. Much of what's needed—common protocol elements, sites, systems, and contracts—is already in place, ready to go. |
| **Accelerated progress** | Trials slot seamlessly into our standardised processes and infrastructure. |

It's mass production for clinical evidence. We're shifting trials from a bespoke "cottage industry" model to a factory model, where precision, speed, and scalability are built into the process. This is the future of clinical research—smarter, faster, cheaper, and better. And it's happening now.

LAYER 1

# Adaptive Trials — The Foundation of Flexibility

Adaptive trials dynamically adjust key elements such as sample size (i.e., when to conclude the trial), trial phase, randomisation ratios, or optimal dose based on accumulating data, improving both efficiency and ethical trial participation.

## Impact

- Faster identification of effective treatments.
- Faster identification of ineffective or harmful treatments.
- Increased speed and resource allocation to promising interventions.

## Our Vision for 2030

Empiric envisions adaptive designs becoming the gold standard for nearly all clinical trials. We will support this transformation through education, advocacy, and harmonised regulatory frameworks.

LAYER 2

# Adaptive Platform Trials — Scaling Efficiency

Adaptive Platform Trials (APTs) leverage shared infrastructure to optimise resources and reduce costs by evaluating multiple interventions simultaneously and using common control groups.

## Impact

- At least 30% cost reduction through shared control groups and infrastructure.
- Faster trial timelines due to the capacity to add new treatments to existing trial infrastructure.

## Our Vision for 2030

Empiric will establish APTs as the default approach for addressing unmet medical needs, particularly in complex diseases. By standardising reusable components such as protocols, recruitment processes, and data systems, we'll accelerate launches, streamline operations, and scale innovation.

LAYER 3

# Platform of Platforms — Scaling Innovation

A Platform of Platforms connects multiple adaptive platforms under a unified infrastructure, enabling simultaneous research across diverse conditions. We will pioneer this approach for rare diseases and rare cancers, overcoming barriers that are unique to conditions with low incidence or prevalence.

## Impact

- Greater scalability to support trials for an unlimited number of diseases.
- Lower barriers to entry for intervention owners through shared governance and resources.
- Better access for those who live with rare diseases and a trial offers the only hope of an effective treatment.

## Our Vision for 2030

Empiric will establish an integrated network of disease-specific platforms, transforming Australia into a global hub for platform-driven clinical research.

LAYER 4

# Technology-Driven Automation — Powering Smarter Trials

Integrating intelligent design and workflow automation eliminates inefficiencies, accelerates timelines, and enhances data availability.

## Impact

- Significant reductions in trial timelines through automated routine tasks.
- Enhanced compliance and data integrity with intelligent systems.

## Our Vision for 2030

Empiric will create an intelligent trial ecosystem that automates processes from protocol design, through recruitment and trial delivery, to in-built implementation of trial results. By embedding automation into every layer, we'll make trials faster, smarter, and more reliable.

LAYER 5

# Embedding Trials in Health Systems — Bridging Research and Practice

Embedding trials within health service organisations (HSOs) aligns research with routine care, transforming how evidence is generated and implemented.

## Impact

- Real-time application of findings, reducing delays in evidence translation.
- Capacity to evaluate existing variation in practice to determine the best treatment option.
- Capacity to evaluate interventions that have previously not been evaluated in trials such as policies and models of care.

## Our Vision for 2030

Empiric will pioneer embedded trials, enabling HSOs to become active research partners. This approach closes the gap between clinical research and practice, ensuring that new treatments are integrated seamlessly into healthcare delivery.

## Our Vision for 2030:
## 10x Smarter and Faster Trials

At Empiric, we believe clinical trials can be:

### 10x Smarter

Enhanced by intelligent design, automation, and scalable platforms.

### 10x Faster

Streamlined through standardised processes and embedded systems.

## Strategic Action Plan

### 1. Innovative methods

Optimise processes to avoid unecessary duplicaiton.

### 2. Invest in Technology

Advance automation and interoperability in trial systems.

### 3. Foster Collaboration

Build partnerships with HSOs, industry leaders, and global stakeholders.

### 4. Educate and Empower

Enable stakeholders with tools to apply faster and smarter clinical trials.

# Conclusion

Adaptive and adaptive platform trials have started to reshape clinical research, but their full potential is vast and remains untapped. By focusing on five transformative layers, Empiric is poised to deliver 10x smarter and faster trials by 2030. Together with our partners, we will revolutionise the industry, ensuring that life-changing treatments reach patients with unprecedented speed and precision.

## Five Layers to 10x Smarter & Faster Trials.