

INTEGRATING NEW APPROACH METHODOLOGIES INTO YOUR THERAPEUTICS DEVELOPMENT RESEARCH

The substantial and rising costs of drug and therapeutics development underscore the need for more efficient and predictive methodologies. New Approach Methodologies (NAMs) aim to streamline early-stage drug discovery and revolutionize preclinical testing by replacing outdated animal-based models with human-relevant insights, directly shortening development timelines and reducing costs. For all their benefits, NAMs do have some limitations, which can be addressed with the right solutions.

In this infographic, we highlight considerations for integrating NAMs into your drug discovery research, including NAM-specific challenges and regulatory guidelines to keep in mind.

THE THREE MAIN CLASSES OF NAMs



IN VITRO

2D cell culture models that utilize relevant human cell types or microphysiological systems, such as 3D spheroid, organoid and organ-on-chip models



IN SILICO

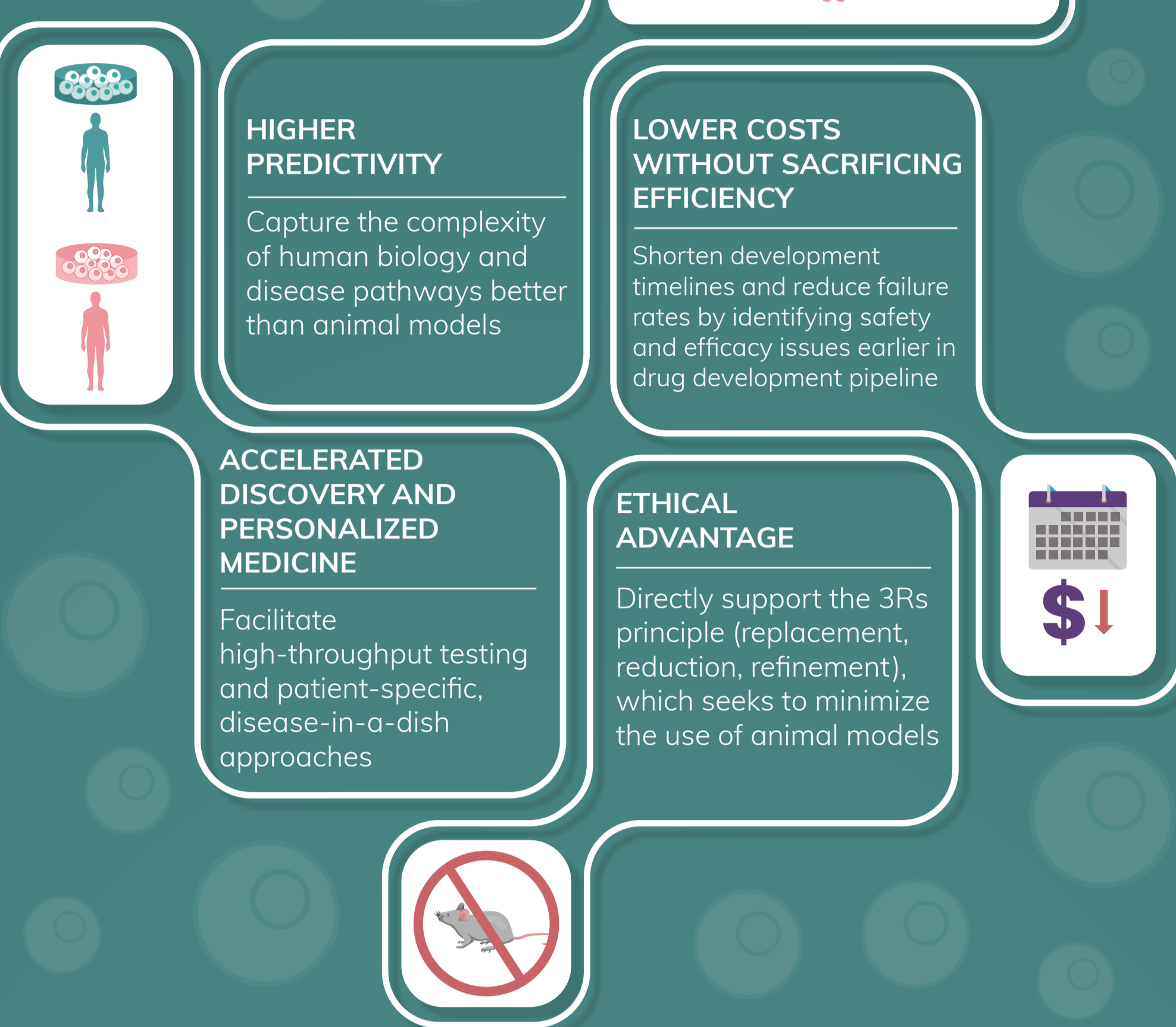
Computational tools that use chemical and biological data to predict and model the properties of a potential therapeutic



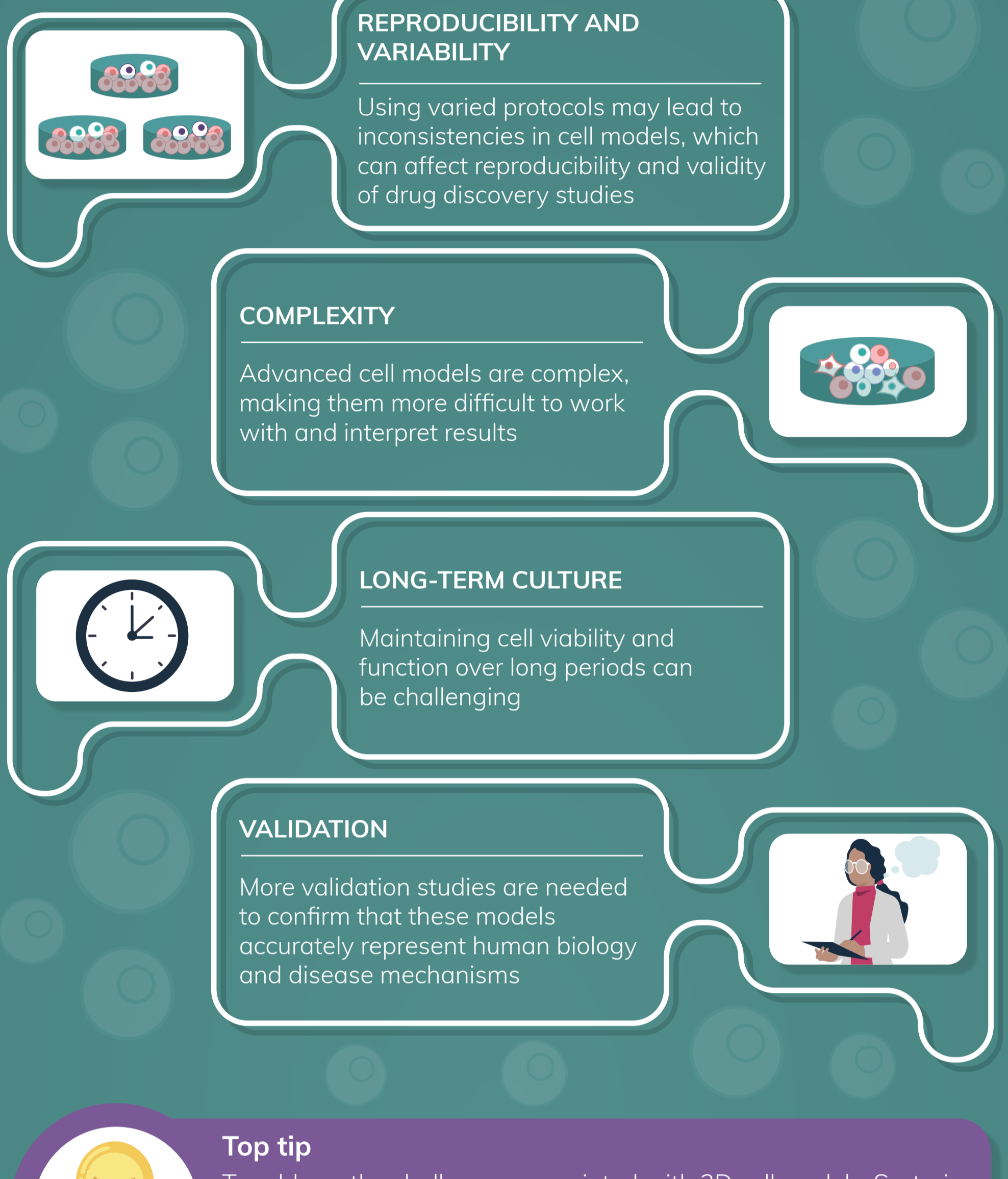
IN CHEMICO

Tests that assess the chemical reactions that occur when substances interact with biological molecules like proteins or DNA

THE BENEFITS

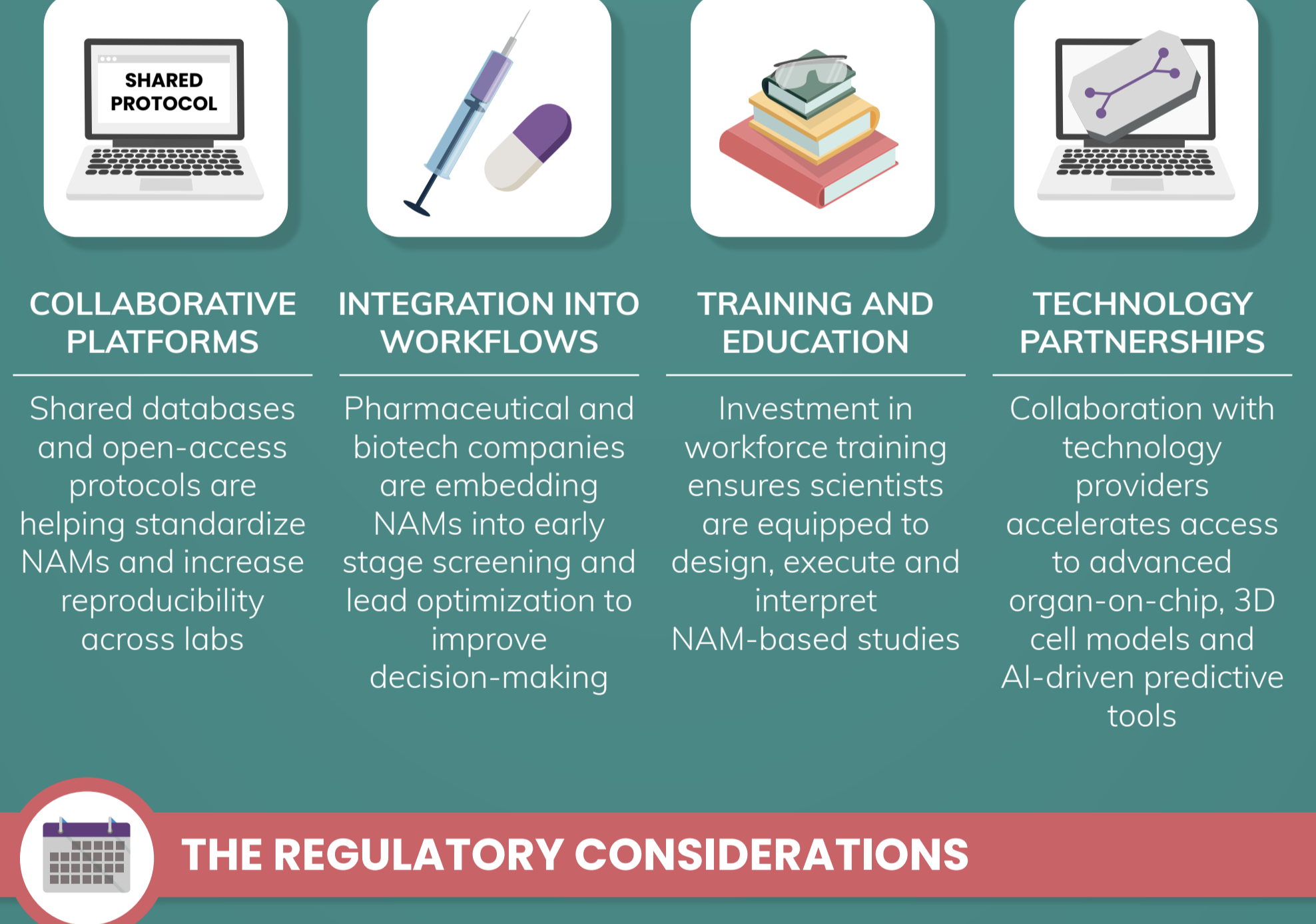


THE CHALLENGES



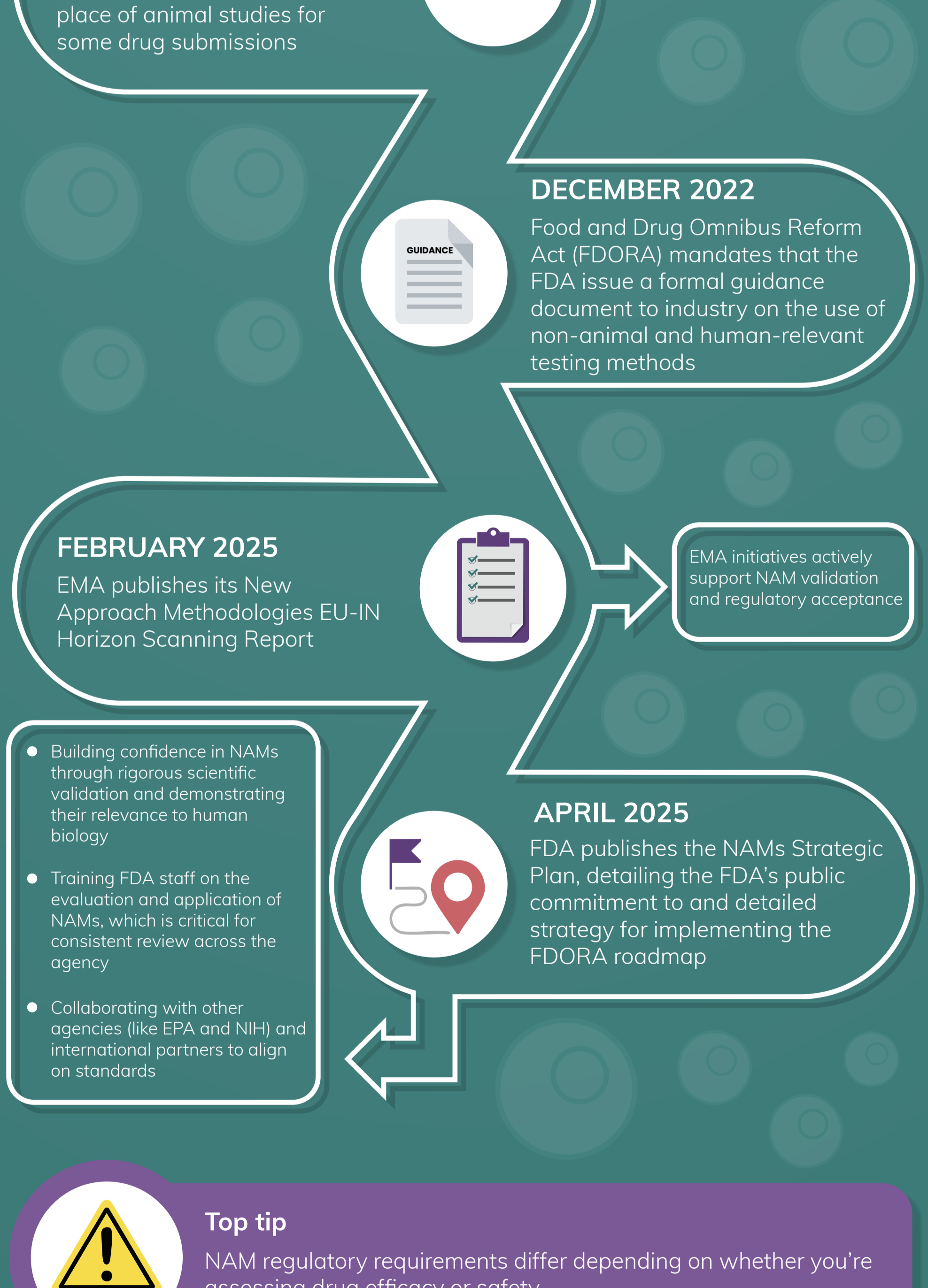
Top tip
To address the challenges associated with 3D cell models, Sartorius provides a live-cell analysis system that collects physiologically relevant data without disrupting cultures. Learn more about the Incucyte® CX3 system [here](#).

THE SOLUTIONS DRIVING ADOPTION



THE REGULATORY CONSIDERATIONS

Before utilizing or developing NAMs in your lab, it's important to consider their regulatory guidelines. Here is a brief timeline highlighting the regulatory landmarks in NAM adoption:



Top tip
NAM regulatory requirements differ depending on whether you're assessing drug efficacy or safety.

- NAMs assessing drug efficacy:** regulatory requirements are not strictly defined for proof-of-concept studies and can change on a case-by-case basis. Researchers are encouraged to contact regulatory agencies early to ensure requirements are met.
- NAMs assessing drug safety:** the regulatory landscape for NAMs in drug safety is evolving. While strictly defined requirements are still limited to specific endpoints, major new guidelines, such as ICH S1B(R1), are now establishing pathways where data from validated NAMs can be required as part of a weight-of-evidence approach to fulfill regulatory obligations.

Regardless of how you are utilizing your NAM for the development of new therapies, it's important to provide clear, comprehensive information about the NAM's context of use.

NAMs are transforming drug discovery by making early-stage research faster, more predictive and ethically responsible. By reducing reliance on animal testing, streamlining preclinical workflows and enhancing human relevance, NAMs offer a path toward safer, more efficient, personalized and cost-effective therapeutic development. As adoption grows and regulatory support strengthens, NAMs are poised to become a cornerstone of modern therapeutic development.

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