Dermatology Innovation Forum
an Advancing Innovation in Dermatology conference

2026 Entrepreneur Bootcamp

Michael D. Howell, PhD; President & Chief Executive Officer, Mountaineer Biosciences, Inc.

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Discovery: It's More Than Skin Deep

Michael D. Howell, PhD

DIF Entrepreneur Bootcamp
Denver, CO
March 26, 2025

MOUNTAINEER BIOSCIENCES

Introduction

MOUNTAINEER BIOSCIENCES

- PhD in Immunology and Microbiology from West Virginia University School of Medicine
- Former Assistant Professor in Pediatric Allergy and Immunology at National Jewish Health
- 25+ years of experience in research and drug development across multiple therapeutic areas
  - Industry experience (Boehringer Ingelheim, MedImmune/AZ, Incyte Corporation, etc)
  - >6 years of C-level experience (DermTech, ZuraBio, Cytoagents)
- Strategic leader for early and late-stage development of small and large molecule assets targeting a wide range of immune pathways (e.g., SKYRIZI®, SPEVIGO®, ADBRY®, SILIQ®, TEZSPIRE®, OPZELURA®, JAKAFI®, tozorakimab, povorcitinib, tibulizumab)
- Inventor on patents for therapeutic interventions and biomarker approaches in immunological disorders
- Experienced company creator for both private biotechnology/pharmaceutical companies

ImmunoBiochem CORPORATION — Drug-Antibody Conjugates

GALILEO — Best in Class AhR Modulators

Triptych THERAPEUTICS — Novel Immunology

SUBTILITAS — Translational & Precision Medicine

I Have an Idea...PROTECT IT!!

What should I do first?

- Disclose the invention to your tech transfer office
- Clarify ownership and inventorship (especially with collaborators).
- File a provisional patent before public disclosure (talks, papers, posters).
- Clarify the licensing terms with the academic institution (royalties, milestones, equity)?

If IP isn’t secured, everything else (funding, partnerships) will be a challenge.

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Scientific & Translational Validity

- What is the precise biological hypothesis, and is it causally linked to disease (vs. correlative)?
- How reproducible are the key findings across models, labs, and datasets?
- What is the minimal viable dataset required to convince investors or partners?
- Is there a validated biomarker strategy to demonstrate target engagement and efficacy?
- How differentiated is this mechanism vs. existing or emerging competitors?
- What is the translational path from model systems to humans?

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Derisking Dermatology Development

In Vitro

Cellular activity

3D *in vitro* cultures

Cellular proliferation & function

Off-target safety screening

In Vivo

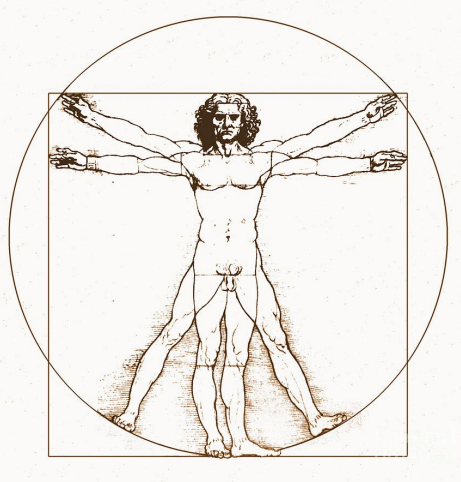
Pharmacokinetics

Pharmacodynamics / target occupancy

Mechanistic models

Disease models

Ex Vivo



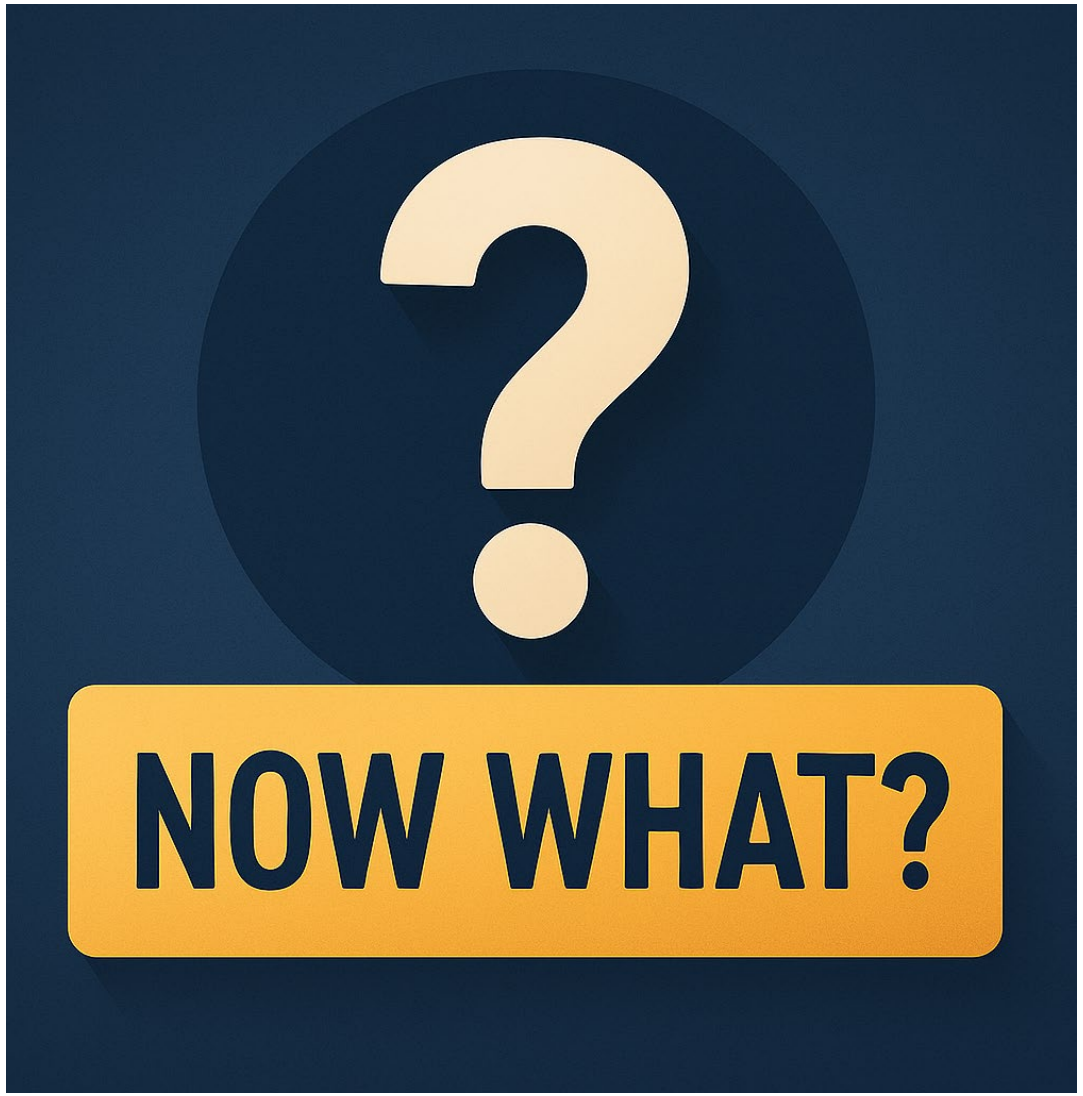
Complex 3D *in vitro* co-cultures

Translational Models

Proteomic / genomic profiling

Cytokine / chemokine biomarkers

Next Steps



- Translate your science into a **clear product thesis**
- Define regulatory path with the U.S. Food and Drug Administration
- Determine the **fastest path to human proof-of-concept**?
- Identify key advisors to support company growth
- Define the **next 12–24 months** in concrete terms

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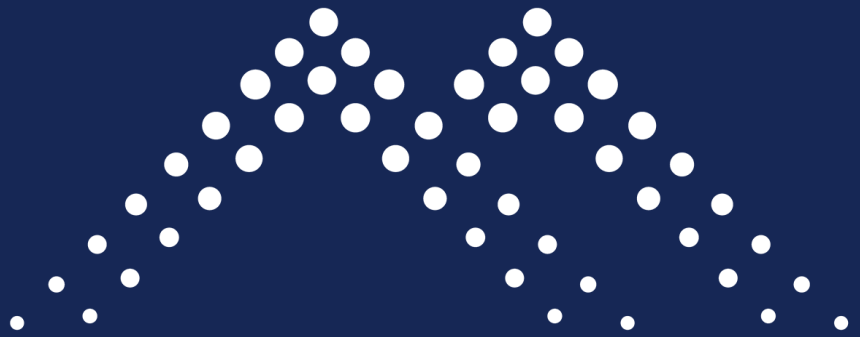

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Entrepreneur Bootcamp

Dermatology Product Development

Vijendra NALAMOTHU, Ph.D.
Founder & CEO
ApoStrata, LLC

From Signal to Story

How early entrepreneurs in pharmaceutical dermatology turn topical science into an investable company

Evidence before elegance. De-risking before scale.

Early evidence | **IP** | **FDA path**

Topical development | **Launch strategy**

For early innovators, the story only works when preclinical signal, formulation logic, IP, and the regulatory route point in the same direction.

- Is it for the right disease? Will it change in the future?
- IP Protection? Now and in the future?
- False +ve and False -ve readouts from early PoC / ex-vivo studies?
- A TPP which is constantly evolving – How to cope with it?
- A regulatory pathway can set you back or propel you forward

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The founder's dilemma: proof-of-concept vs. financeable studies

- Early Formulations: DMSO Solutions vs. Prototype Formulations?
- Maximum Concentration vs. Maximum skin penetration?
- Are the formulations stable?
- Start with disease-specific formulations early on!
    - How will the formulation evolve with progression of clinical studies and the collaborator
- *In vitro* vs *in vivo* vs. *ex-vivo* PoC models: Is this data for you or for the investors?
- Reasonable and translatable animal / disease models
- Investors tend to always ask for the skin penetration data
- Molecule's efficacy PoC models always does not translate to human PoC data
- Don't forget the need for the derm safety / skin tox data

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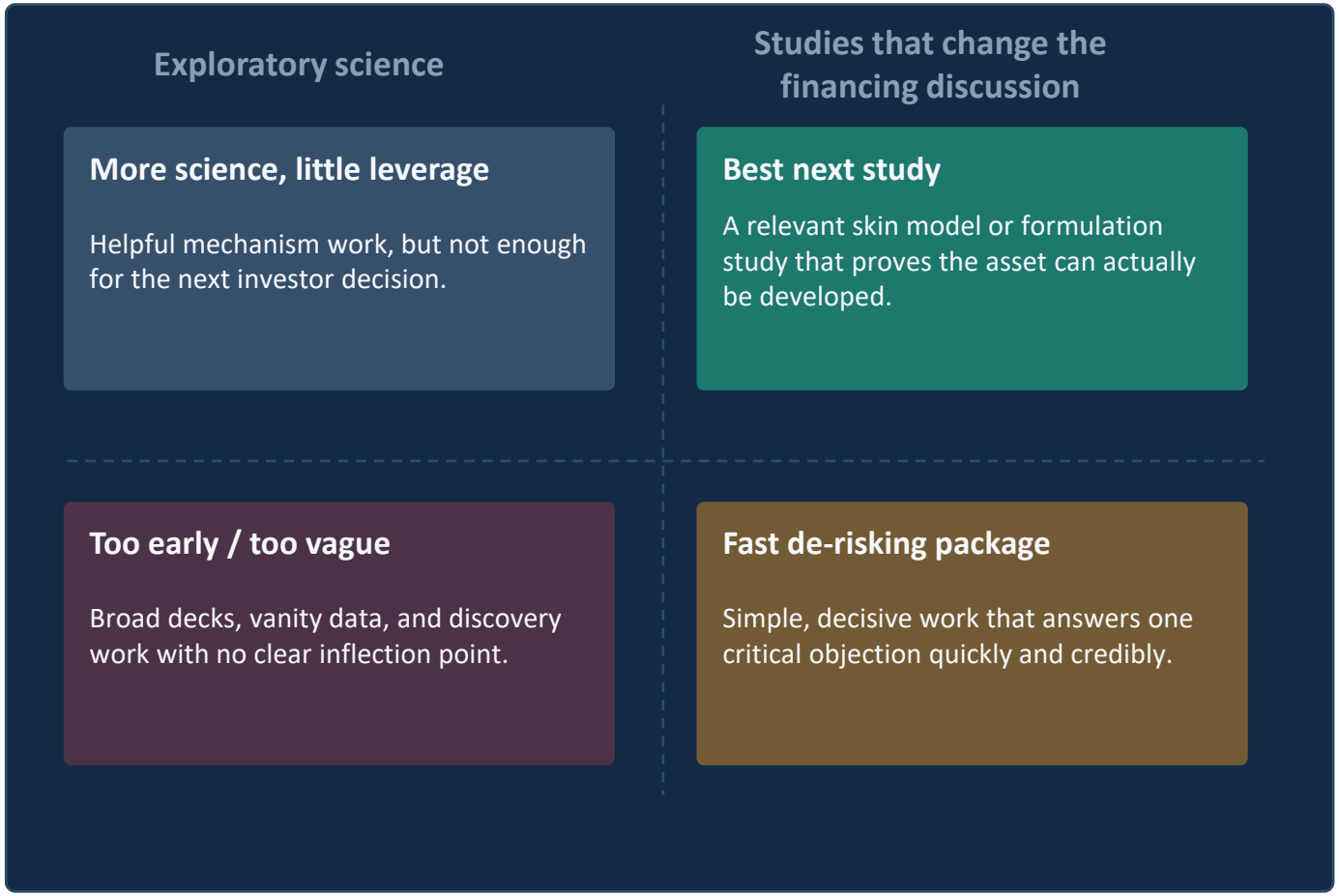
The founder's dilemma: proof-of-concept vs. financeable studies

The best next study is the one that removes the next financing objection.



For topical dermatology, early evidence should prove four things:

- The biology works in skin, not only in a broad *in vitro* screen.
- The dosage form can release and deliver drug where the target biology sits.
- Local and systemic safety look manageable early enough to keep going.
- The formulation behaves reproducibly enough to become a product, not just an idea.

Financeable data package > beautiful science alone

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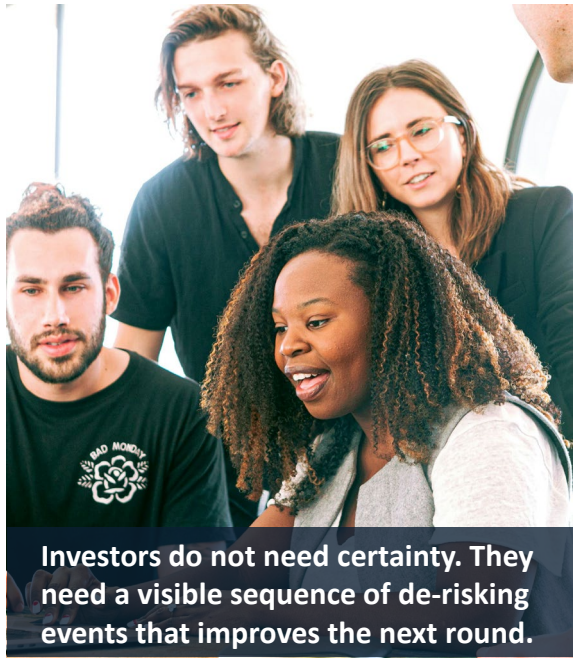
Molecule: Supplies; IP & Regulatory Strategy

- Is it a New Chemical Entity (NCE) or a known molecule?
- Mfg. scalability of the NCE / drug substance: mg. vs. kg. quantities; impurity profiles; cost of the material; vendor qualifications; quality agreements etc.
- Early formulations / pre-clinical supplies (non-GMP material) vs. Clinical supplies (GMP material): evolving IP
- If it is a known molecule, what is your IP positioning?
  - Method of use / Formulation Patents / Orange Book Exclusivity
  - FTO: A continuous check
  - Strong IP is Investor-friendly & long-term defense strategy
  - Multiple patents / CIP
- 505(b)(1) vs. 505(b)(2) vs. 510(k) :: Cosmetic / Medical Aesthetic / Cosmeceuticals / OTC
- Pre-IND meeting with FDA and a structured project progression plan always gains investor confidence
- Clinical Studies in US vs ex-US and FDA's concurrence on the early safety and clinical studies done outside of an IND
- A regulatory pathway can set you back or propel you forward

Commercial (Product) Strategy

- A Target Product Profile (TPP) is a constantly evolving topic amongst the innovators, strategic partners and investors
- Compare & evaluate the product / formulation carefully against the market leader(s) to gain investor confidence
- A balance of product image – clinical evidence – commercial strategy wins the deal.
- Product differentiation is good but should not be the only strategy
- A preliminary analysis of COGS, NPV, market segmentation, and market capture/positioning can help present your product more credibly and create stronger investor optics



Unmet need	Is the disease burden obvious, and is there a practical entry indication?
Differentiated asset	Is this better than “another cream” because of biology, delivery, convenience, or tolerability?
Visible de-risking	Will the next studies make the biology and development risk materially smaller?
Strategic leverage	Do IP and the regulatory pathway create time, optionality, and partnering value?
Capital efficiency	Does this round buy a specific value inflection in roughly 12–18 months?

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When do you advance an idea into development?

Advance when the next dollar buys execution more than open-ended exploration.

1	**Signal in skin**	A relevant preclinical or translational model shows repeatable activity at a realistic dose.
2	**Formulation behaves**	The cream, gel, foam, lotion, or ointment shows release, permeation, stability, and manufacturability logic.
3	**Moat is defendable**	Composition, method-of-use, or process claims are visible, and freedom-to-operate hotspots are understood.
4	**FDA route is credible**	You can explain whether the product looks more like 505(b)(1), 505(b)(2), 505(j), or an OTC strategy — and why.
5	**Market wedge is real**	A lead indication, prescriber segment, and access story are narrow enough to win first.

Founder rule: if the next critical work looks like formulation, IP, pathway, and launch preparation — not just more discovery — the idea is ready to enter development.

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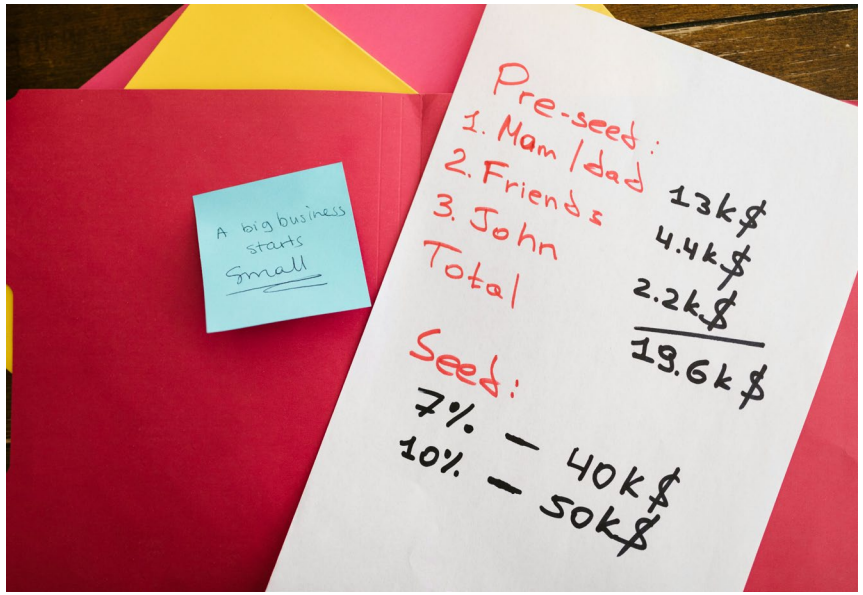
How do you support the capital raise?

Raise money for a proof point, not for general exploration.

What belongs in the raise package

- A target product profile with one lead indication and a clear treatment gap.
- A study plan explicitly tied to investor objections: biology, delivery, safety, or manufacturability.
- An IP plan: what is filed now, what data will strengthen later claims, and where FTO needs attention.
- A preliminary FDA path that tells investors what kind of evidence may matter most.
- A use-of-proceeds plan showing which milestones change valuation or partnering leverage.

Good capital support translates science into milestones, ownership of risk, and timing of value creation.



Milestones this round should ideally buy:

- Formulation lock + stability logic
- Translational or preclinical proof that reduces biology risk
- Stronger IP position and a clearer FDA development route

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Topical dermatology development and launch strategy

In this category, dosage form, regulatory route, and launch wedge are part of the same story.

1 Preclinical signal + formulation concept	Start with relevant skin biology and a dosage form choice that already matches where the drug needs to act.
2 Translational package	Build release, permeation, stability, and early safety data that make the formulation believable as a product.
3 CMC + FDA route	Use the emerging data package to sharpen the likely pathway, evidence strategy, and development cost profile.
4 Clinical design	Choose the fastest credible clinical plan for the lead indication, with endpoints that matter to regulators and prescribers.
5 Commercial wedge	Launch first where prescribers concentrate, differentiation is visible, and access can be won with focused resources.

Early launch logic

- one focused indication
- tight KOL and prescriber map
- payer / access story early
- partner-ready package if scale demands it

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Early Study Design Strategy

Proof of Mechanism (PoM) vs. Proof of Concept (PoC)

Jasmina Jankicevic, MD, MSc, CCRP
Chief Medical and Scientific Officer

Agenda

01
Proof of Mechanism

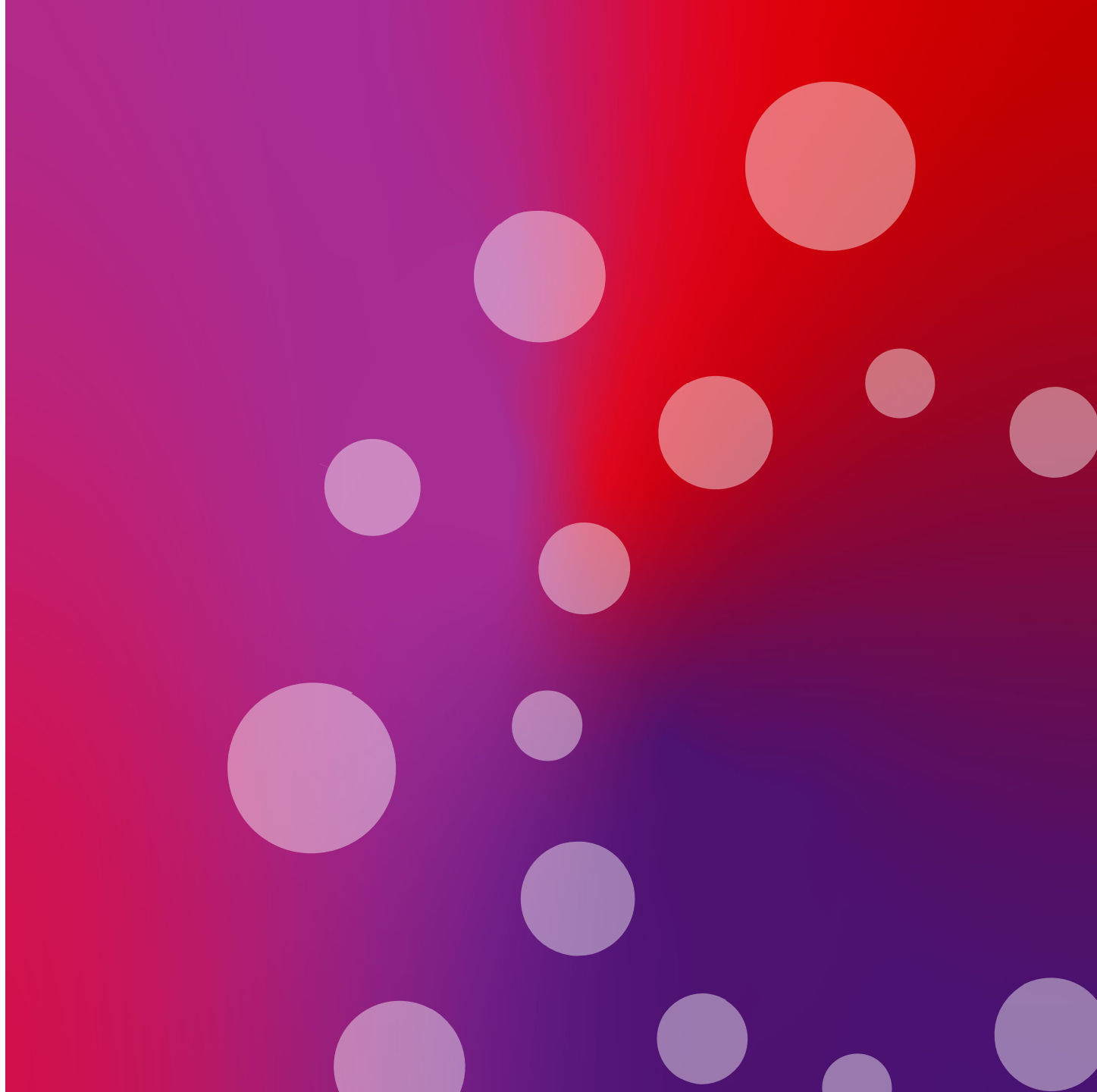
02
Proof of Concept

03
Making the Most of the PoC Study

04
Balancing Curiosity, Relevance, and Feasibility

01

Proof of Mechanism



PoM is an Early “Sanity Check”

Key Question:

- **Does this drug actually do what it is designed to do at the molecular level?**

Components of the approach:

1. ***Exposure at the Target Site*** – Proof that the drug reaches the intended site at a concentration high enough to be active
2. ***Target Engagement*** – Proof that the drug molecule physically binds to or interacts with the intended receptor, enzyme, or protein.
3. ***Functional Modulation*** – Proof that the binding results in the intended biological "spark" (e.g., inhibition of a kinase, release of a cytokine, or change in gene expression).

Preclinical PoM Necessity

Pharmacological bridge

- Prove that the molecule's chemical design translates into the intended biological behavior in controlled lab environments.
- Focused on the "how" and "where" at the molecular and cellular levels.

FDA Draft Guidance:
New Approach Methodologies (NAM) in Drug Development

Validation Considerations:
(1) Context of use
(2) Human biological relevance
(3) Technical characterization
(4) Fit-for-purpose.

Model Systems

- **In vitro (cell-based):**
  - Target Binding Assays
  - Signal Transduction Mapping
  - Cellular Functional Assays
- **In vivo / ex vivo methodologies**
  - Organoids
  - Organ-on-a-chip
  - AI-driven in silico models
  - Animal models (only if you can’t demonstrate higher human biological relevance of any NAM)

Biomarker Bridge

- Identification of a translatable (primary PD) biomarker(s).

Clinical PoM-based Decision-Making

Go/No-Go

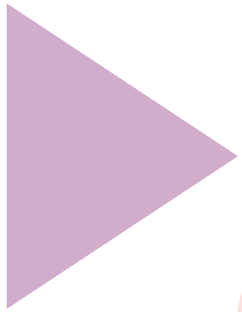
- The ultimate output is a **PK/PD Model**.
  - **If exposure/binding is high but the effect is low:** The target itself may be the wrong one for that disease.
  - **If exposure is low:** The delivery system (e.g., pill vs. injection) or dose is likely inadequate.

Clinical Insight

- A successful PoM in human blood (systemic PK) and skin tissue (local PD) drastically "de-risks" a drug. If you prove the mechanism in Phase 1, the chance of failure in Ph2b and Ph3 due to "lack of efficacy" drops.

Keeping the Perspective

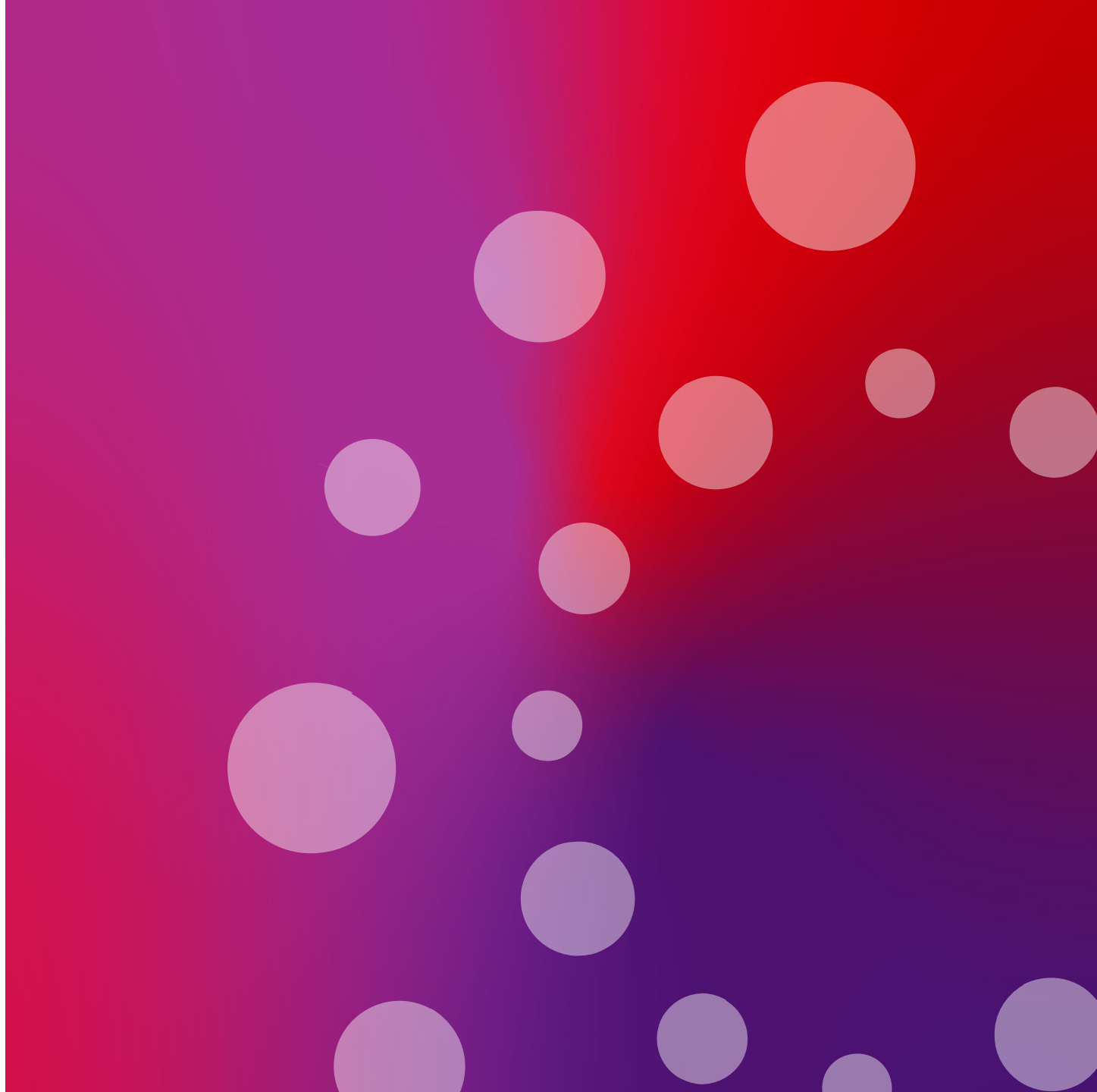
Preclinical PoM is the "Laboratory Truth,"



Clinical PoM is the "Biological Reality."

02

Proof of Concept



PoC Study – The Best Road to Success
(or Early Failure)

Key Question

Does hitting this/these targets treat the disease?

Did participants on MIP get better?

The Ph1b/Ph2a must show a statistically significant effect (or at least a clear signal) on clinical endpoints (or acceptable surrogates) that **strongly predict clinical benefit**.

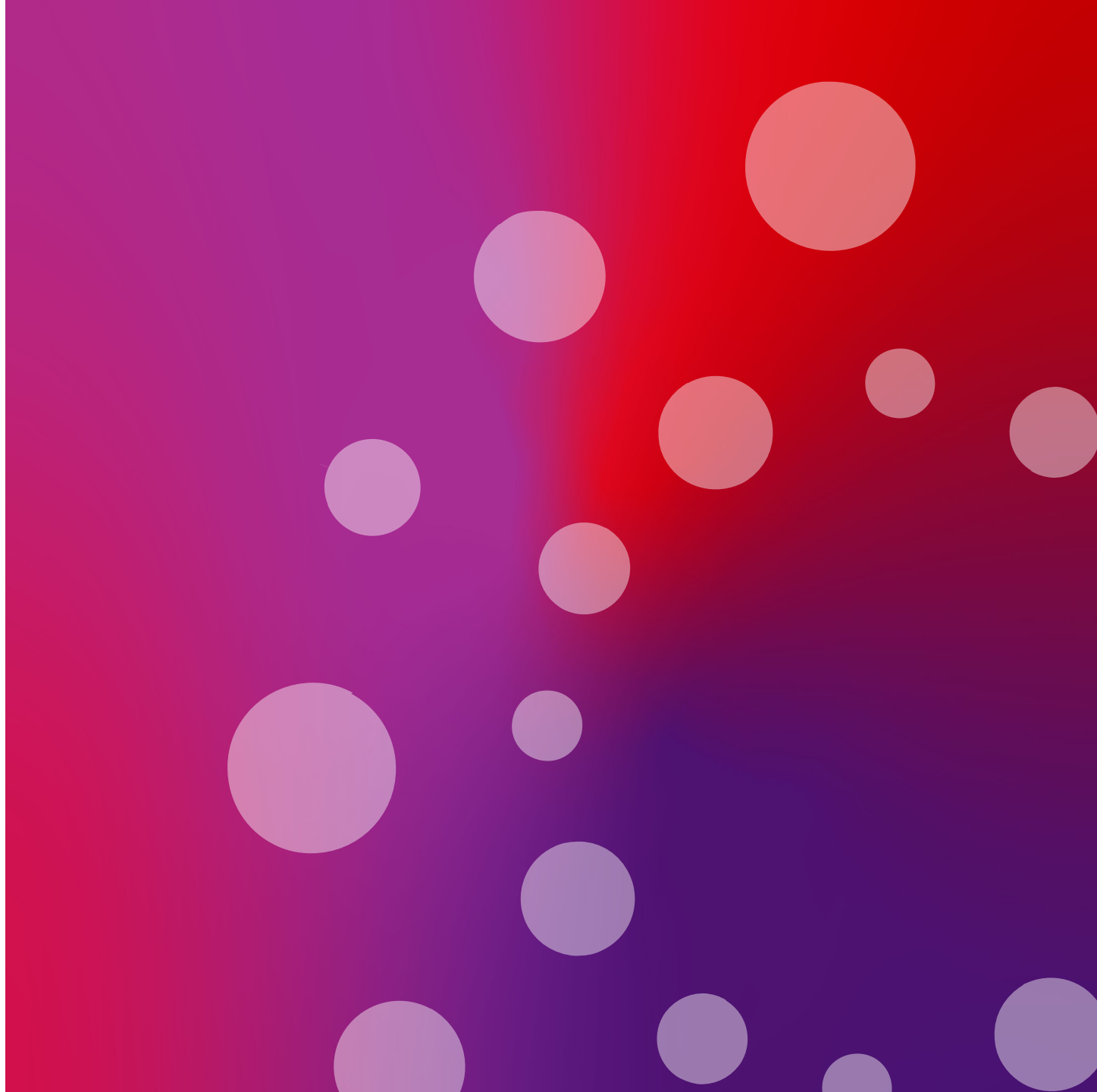
Objective: To demonstrate that the **mechanism of action results in a clinically meaningful benefit.**

Key endpoints: **ClinROs & PROs**

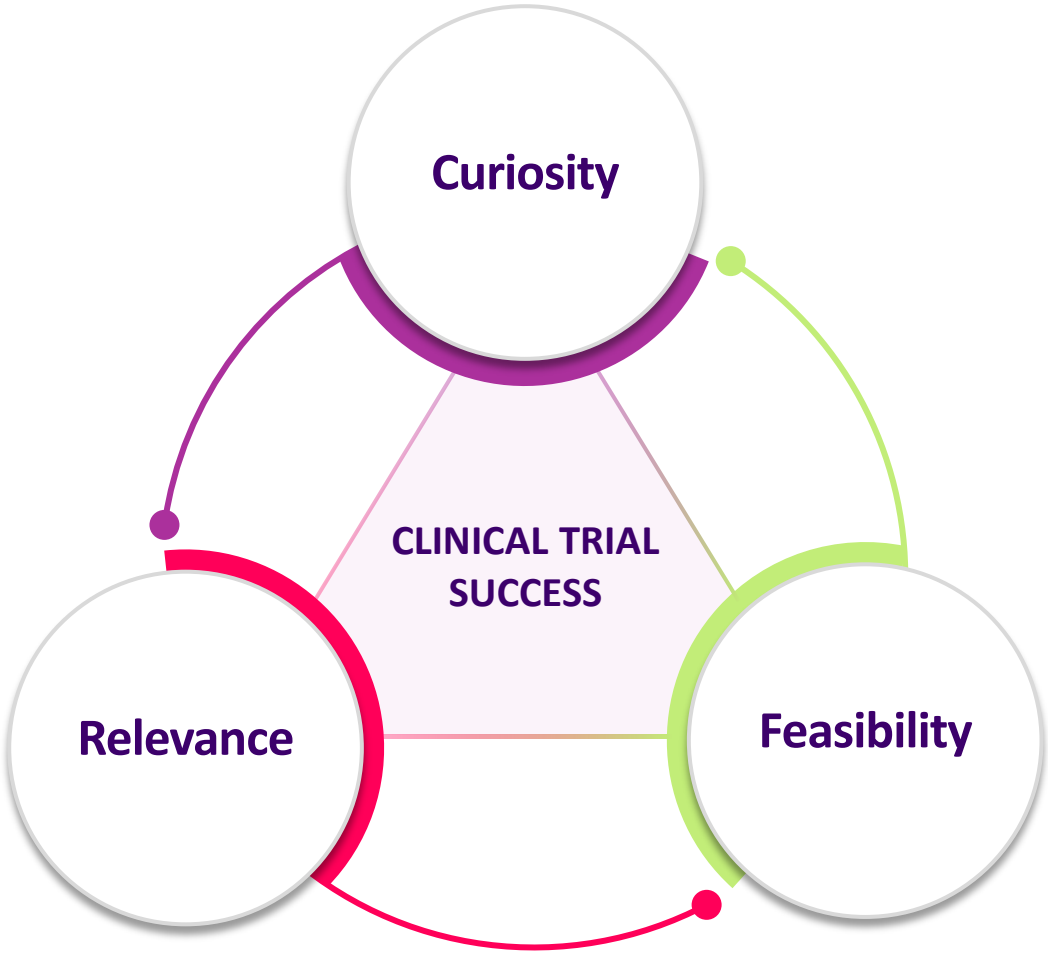
Significance: A successful PoC is a long-awaited "Green Light" for the massive financial investment.

03

Making the Most of the PoC Study



Find the Right Balance



Importance of Curiosity in PoC Study

INNOVATION

Design creativity – inter/intra-patient design;
Rando-DB vs. OL; sequential/parallel/cross-over

PROBLEM-SOLVING

Address key scientific and medical questions

OPEN-MINDED

Think outside the box (e.g.,signal-seeking approach - correlation of biomarker and clinical outcomes; active comparator)

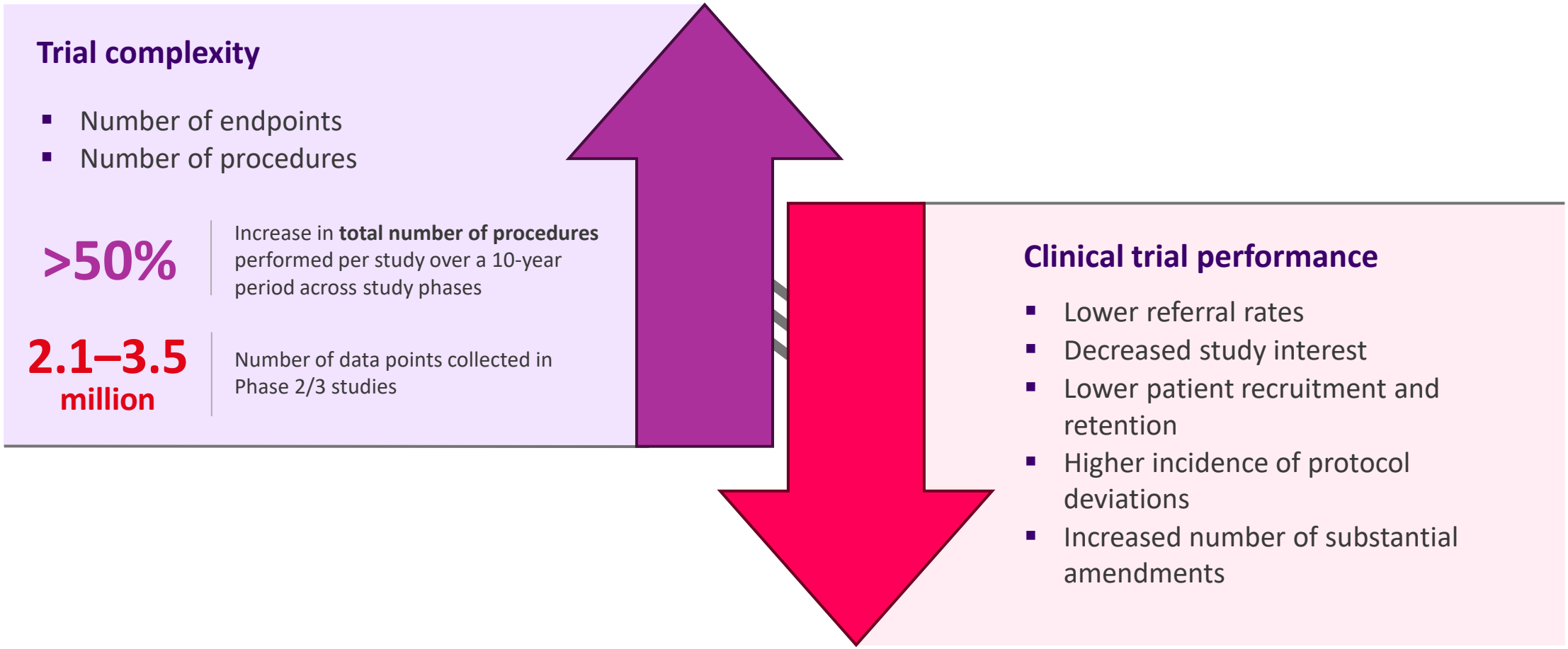
COLLABORATION

Synergize SMEs

New effective/safe treatment option attracts investments

Pitfalls of Curiosity

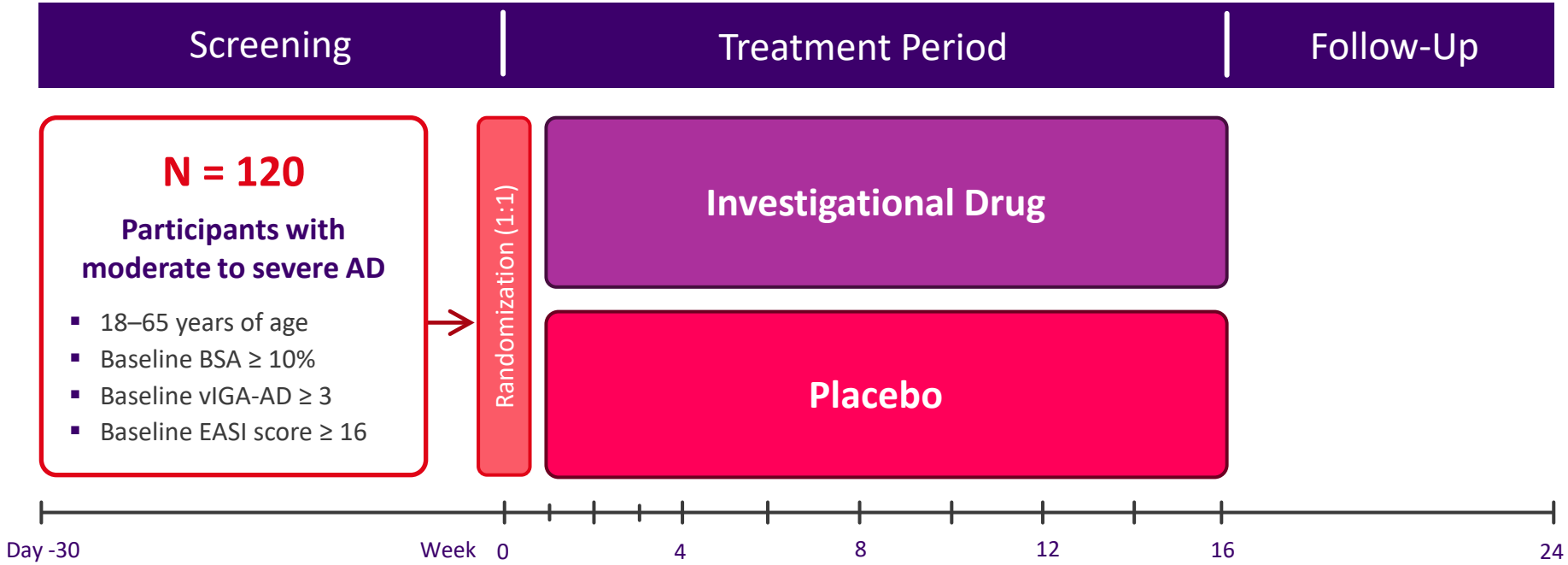
Curiosity can translate into **heightened trial complexity** by increasing the number of explored endpoints and number of procedures performed, ultimately impacting the overall **performance of a trial**.



Getz et al. 2023.

Case Study: Hypothetical P1b/2a AD Study

This is a hypothetical Phase 1b or Phase 2a, double-blind, placebo-controlled, randomized clinical trial to investigate the efficacy and safety of an investigational drug compared with placebo in adult participants with moderate-to-severe AD.



Primary Efficacy Endpoint

Percentage change from baseline in EASI at Week 16

Efficacy Assessments

- EASI
- BSA
- vIGA-AD
- TEWL
- Photos
- DLQI
- POEM
- SCORAD
- RECAP
- ADCT
- Itch NRS
- SD-NRS
- Serum biomarkers
- Skin biomarkers
- Pharmacogenomics
- Anti-drug antibodies

≥ 50% of participants must have **severe AD** at baseline

6 Skin biopsies

8 Tape strip samples

16 Blood samples

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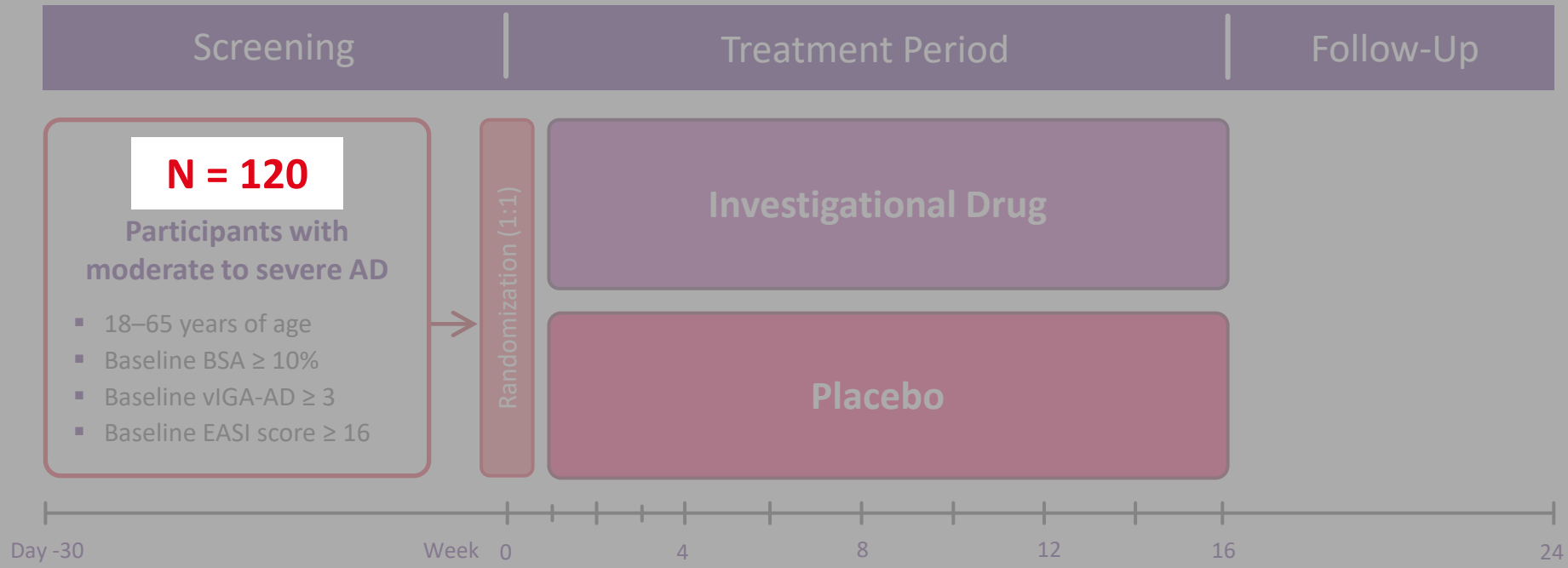

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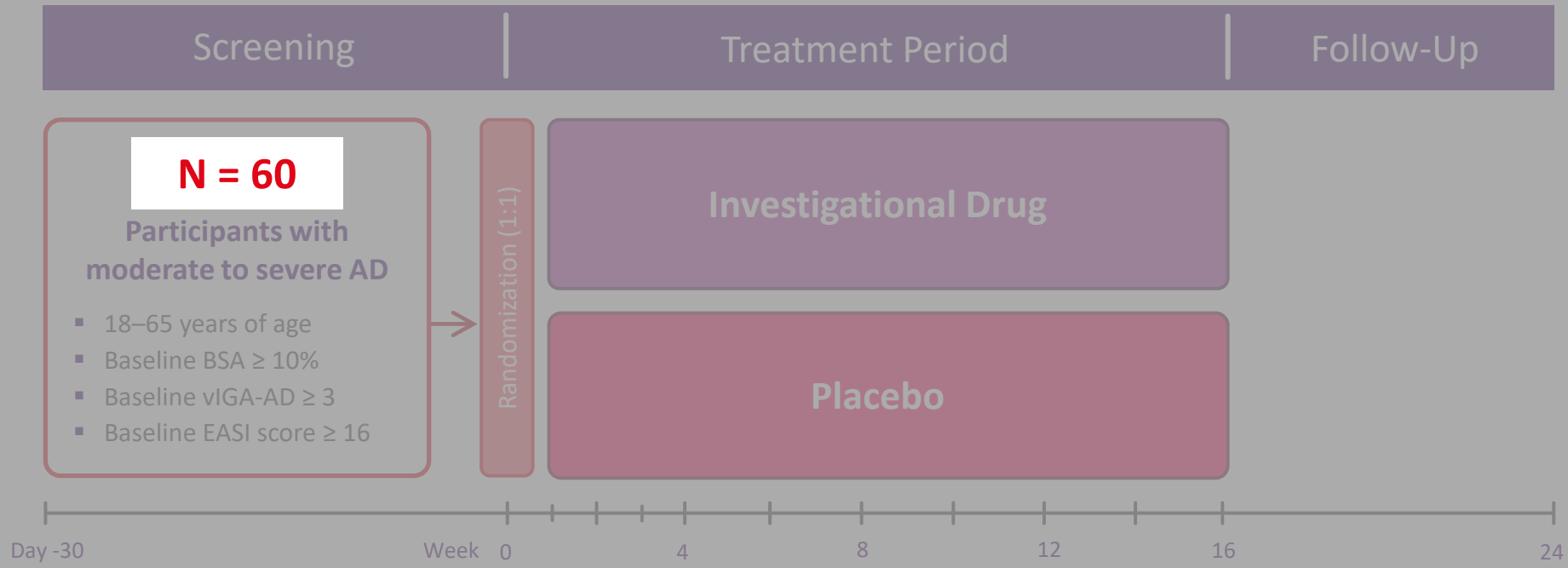

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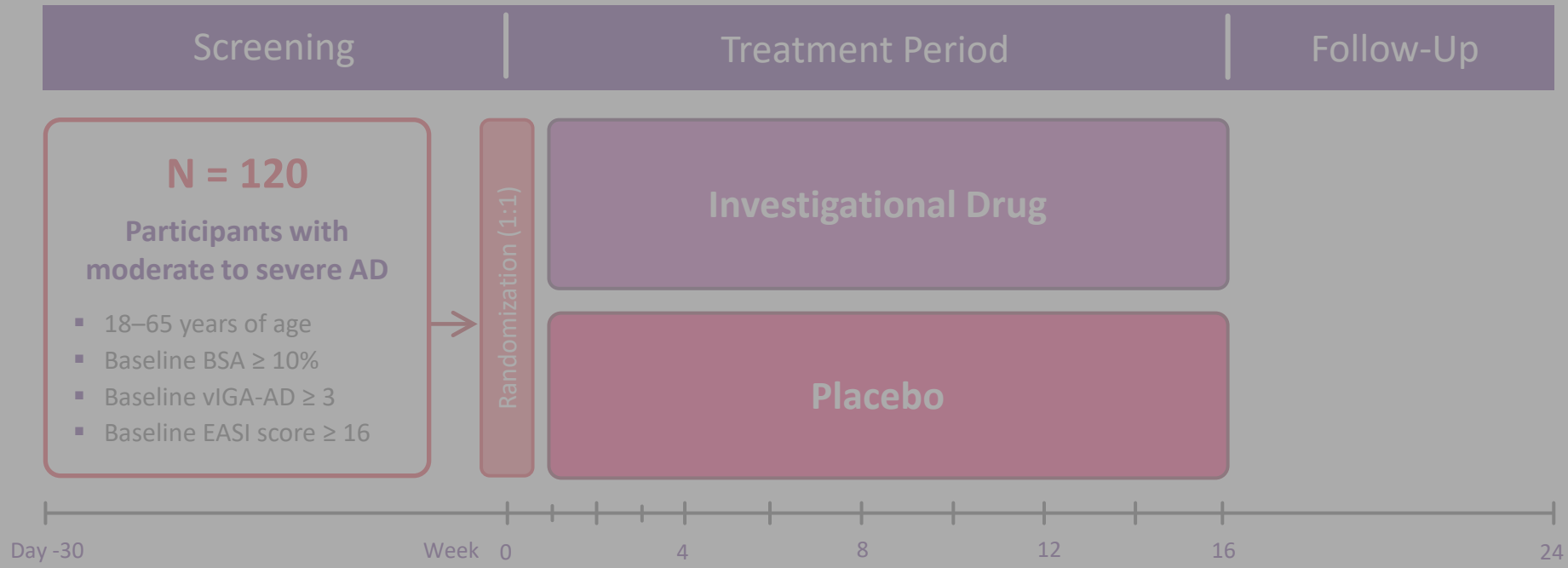

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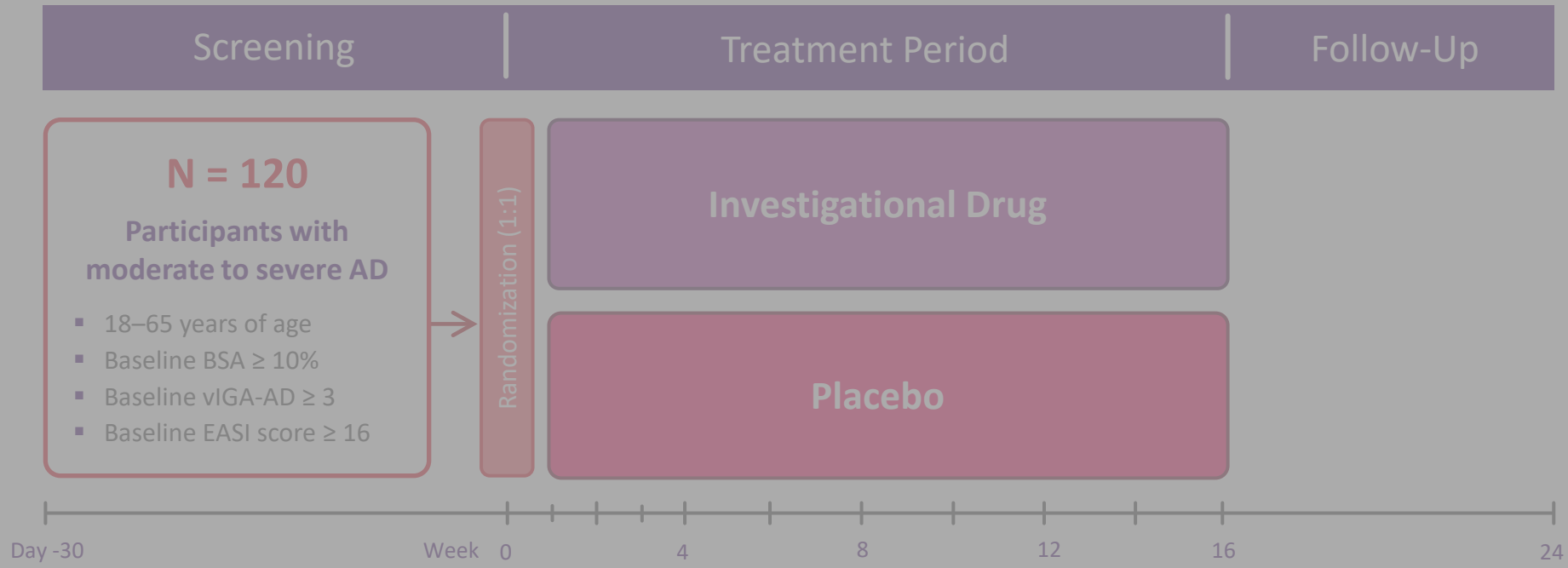

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4 Skin biopsies (subset)

8 Tape strip samples

8 Blood samples (subset)

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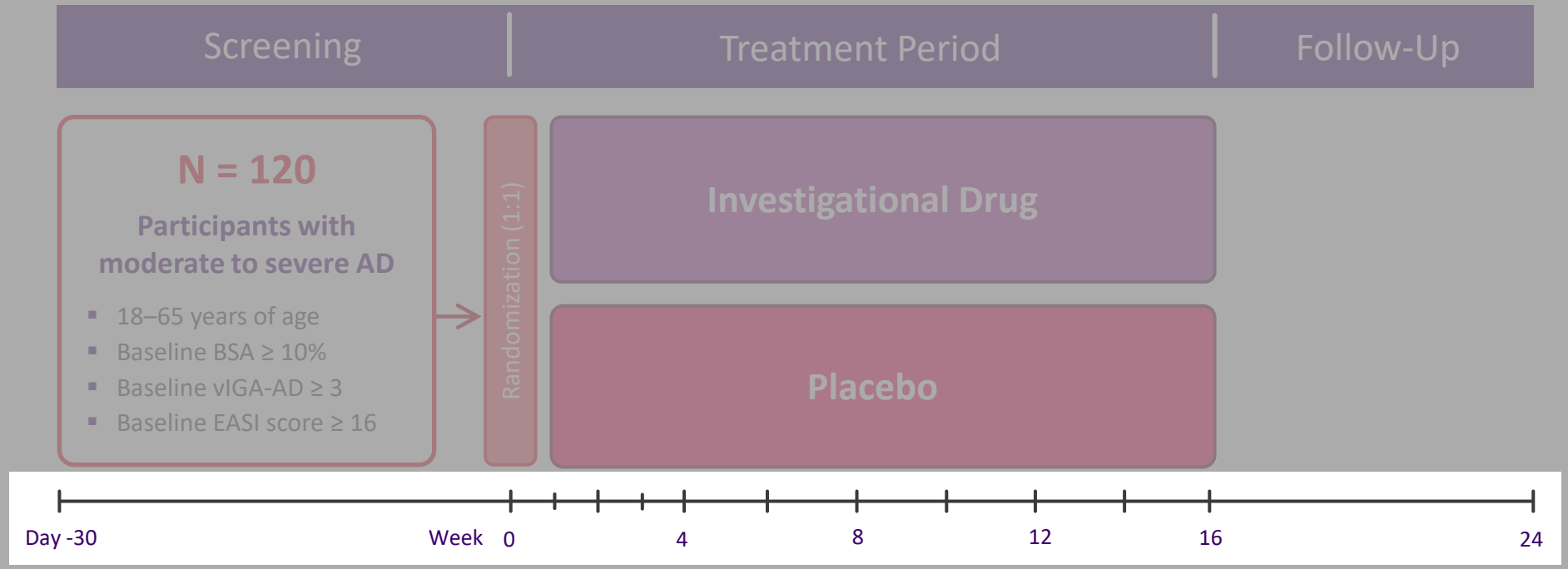

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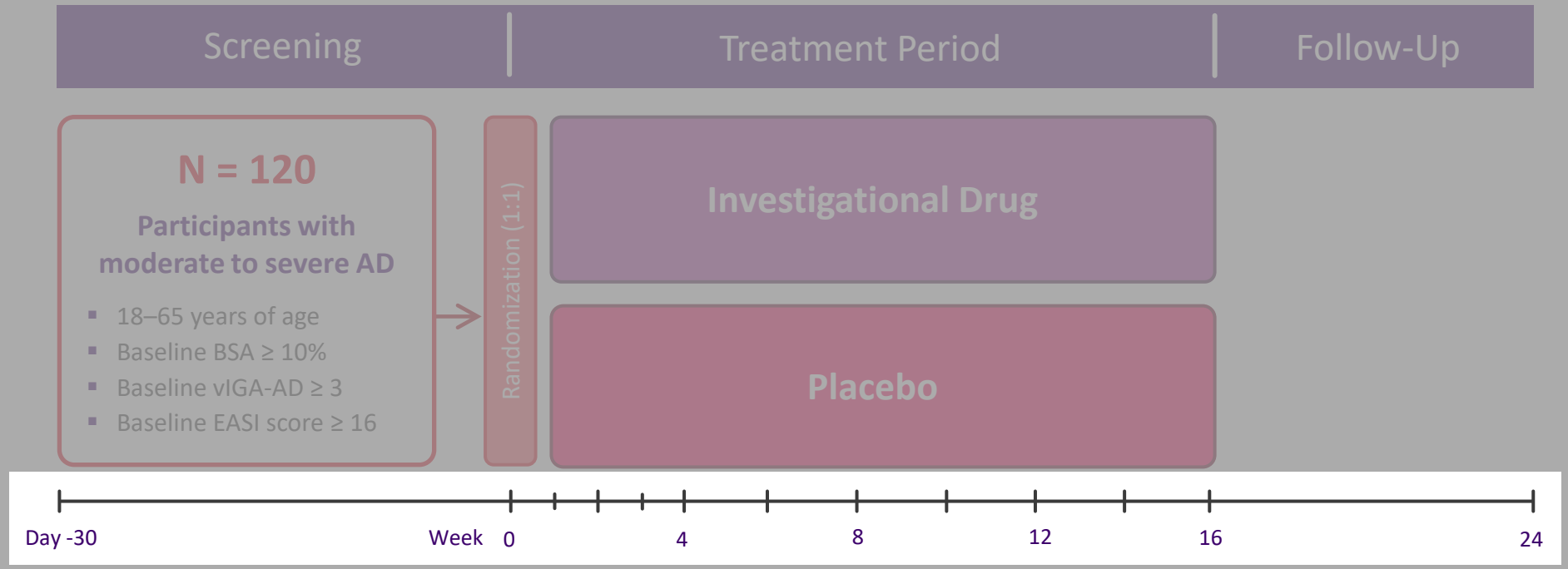

Primary Efficacy Endpoint

Percentage change from baseline in EASI at Week 16

≥ 35% of participants must have **severe AD** at baseline

New P1b/2a AD Study Scenario – Challenge it Further

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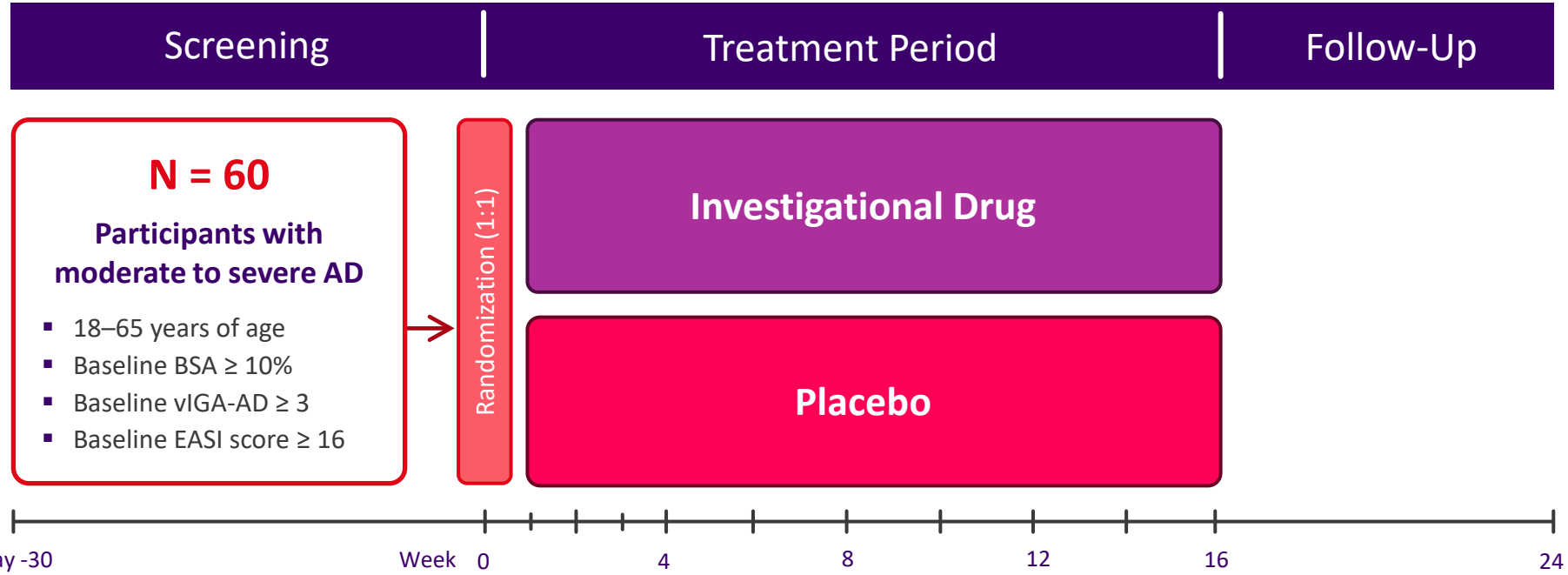

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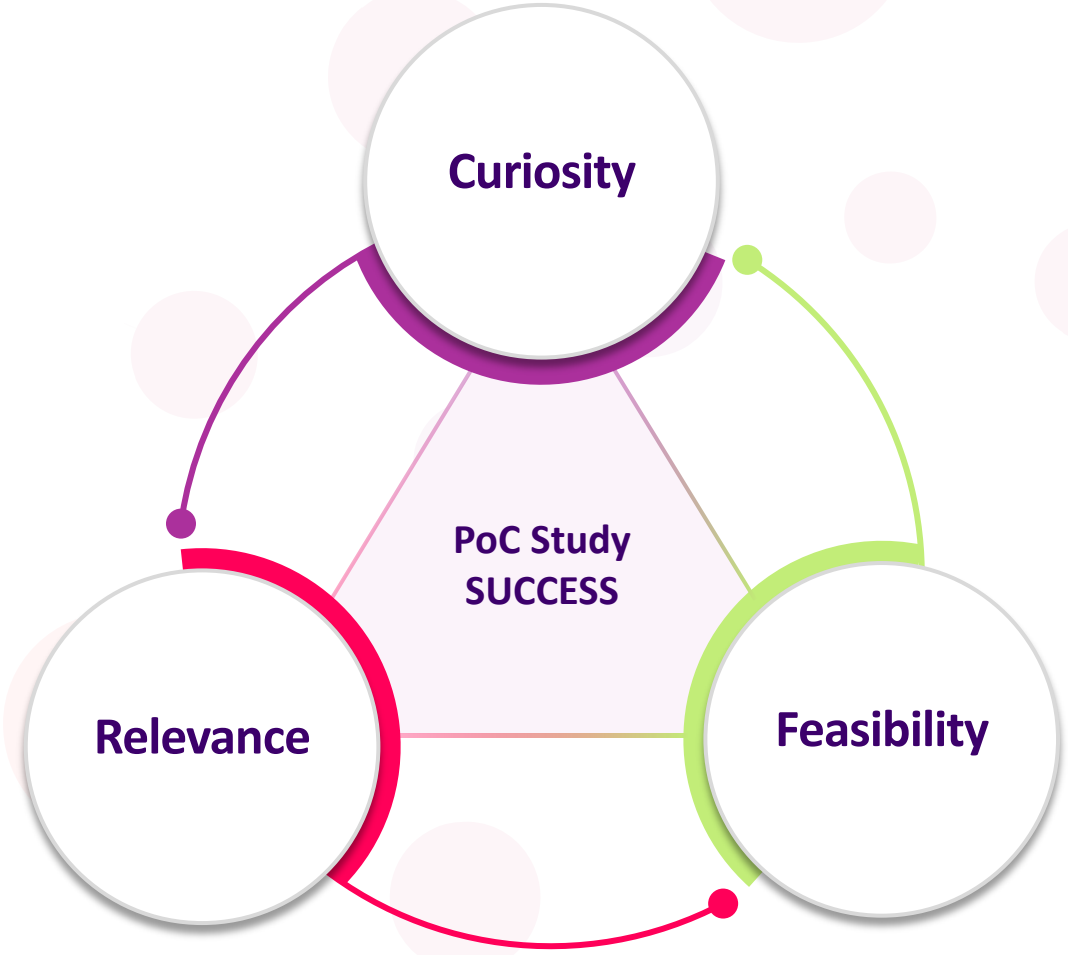
2 Skin biopsies

8 Tape strip samples

6 Blood samples

Conclusions

- Start with a pre-clinical PoM
- Incorporate human PoM principles into PoC to enhance study output
- Reduce cost and timelines by doing what is necessary – not more, not less
- Gather SMEs to optimize design and implementation



Thank you!

Jasmina Jankicevic, MD, MSc, CCRP

dr.jasmina.jankicevic@gmail.com

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