Does the Practice of Implementation Science have a place in Industry-Sponsored Research?

Your speakers today

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Models, Methods & Measures in Drug & Device Development

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Knowledge Translation (KT) and Implementation Science (IS)

Knowledge Translation

- [The] exchange, synthesis and ethically-sound application of knowledge (within a complex system of interactions among researchers and users)
- To accelerate the capture of benefits of research through improved health, more effective services and products, and a strengthened health care system

(Canadian Institutes of Health Research [CIHR], 2015)

Implementation Science

- Implementation science is the study of methods and strategies to promote the uptake of research findings and evidence-based practices into regular use by practitioners and policymakers
- It aims to understand and address the barriers to effective implementation and to develop approaches that improve the quality and effectiveness of health services, education, and other fields

(Proctor et al, 2013)

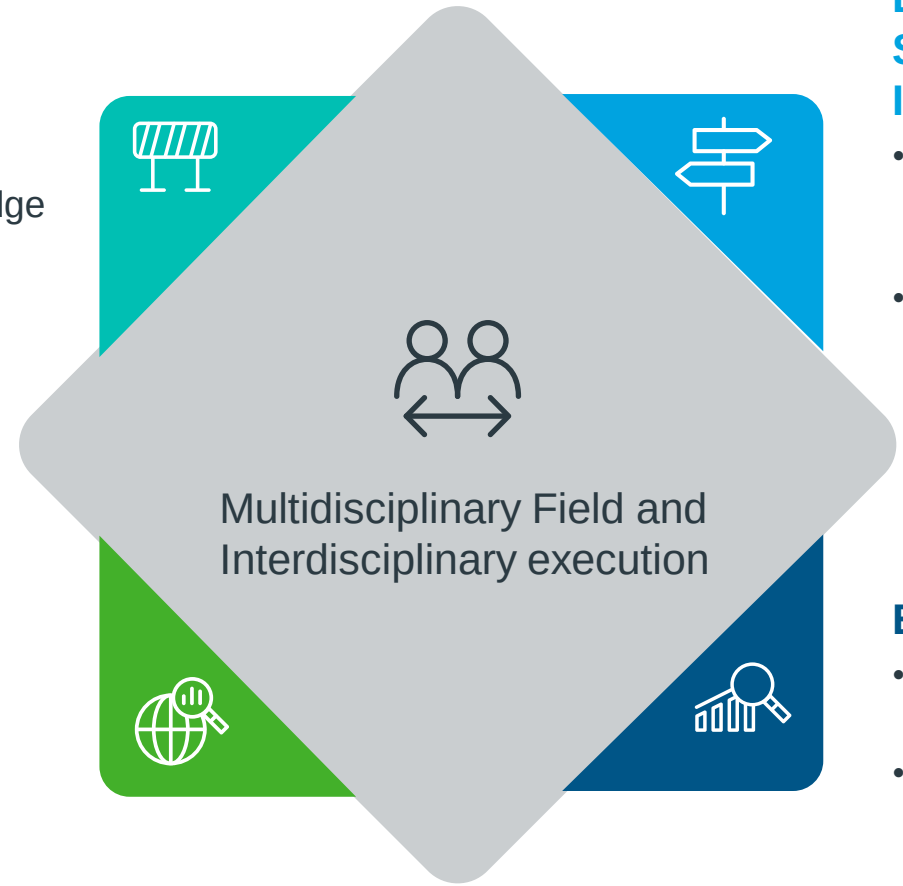
Key Aspects of Implementation Science

Identify strategies that ensure research evidence access to Knowledge Users

- Identifying barriers and facilitators
- Engaging every contributor of knowledge use
- Co-designing, stakeholder input

Development of Implementation Strategies or Evidence Interventions

- Methods to enhance the adoption, implementation, and sustainability of evidence-based interventions
- To overcome barriers and support facilitators



Adaptation of Implementation Strategies or Evidence Interventions

- For application by knowledge users

Evaluating Outcomes

- Assessing the impact of these interventions on practice and policy
- Assessing sustainability

The Evolution of Implementation Science

Other terms that have been used:
- Research utilisation
- Knowledge utilization
- Diffusion of innovations
- Technology transfer
- Evidence-based medicine
- Quality improvement
- Knowledge management
- Knowledge translation

Wave 1: 1920-1960

- Research Committee on Social Trends (1929): first official initiative designed to maximize the impact of science on society's needs
- 1930-1940: application in agriculture
- **1962: Diffusion of Innovative Theory (Influential decision theory) (Rogers)**

1972

- ***"Knowledge Translation"* first used in French Canadian article,** discussing measures to promote application of lab discovery to improved diagnosis or treatment in clinical care
- National Institutes of Health's (NIH's) Roadmap for Medical Research has labelled T1 or "bench to bedside KT"; with T2 describing the rest of the continuum (i.e., namely, the transfer of findings from clinical studies to practice settings)

1990s

- Strategic partnerships between federal and local agencies to transfer knowledge into action to improve health, education, and human services
- **Canadian Health Services Research Foundation (CHSRF) in 1996**

Year

Wave 2: 1960-1980

- Focus on innovation adoption by both individuals and organizations
- National investments largely motivated by the goal of stimulating economic growth through advancing technology and a need to increase the application of innovations emerging from various areas of research (e.g., **defense and space; health, education, and human services**)

Wave 3: 1980-1990

- Test the effectiveness of dissemination and utilization strategies
- Distinct **field of professional and scholarly activity**
- **Reagan administration**

2000s

- 2000: Canada: **CIHR's role in promoting KT and IS through funding and policy initiatives**
- 2006: USA **NIH's** emphasis on Clinical and Translational Science Award Program
- 2006: the **Cooksey Report** in the United Kingdom
- 2012: USA, National Research Council, within the field of disability and rehabilitation research, NIDILRR steered early and influential IS work

How adoption of evidence can be accelerated through IS

Preclinical Research

- **Challenge:** High costs and lengthy timelines for developing new drugs and treatments
- IS optimizes research processes, reduces costs, and accelerates development by identifying effective strategies and addressing barriers early on

Regulatory approval

- **Challenges:** Ensuring efficient and effective clinical trials, Navigating complex regulatory requirements.
- IS frameworks streamline trial processes, optimize endpoints, and accelerate trial start-up times, improving overall trial efficiency
- IS helps streamline compliance processes, ensuring new products meet regulatory standards efficiently

Payer decision-making

- **Challenges:** Balancing the need for affordable pricing with the financial viability of new products
- IS helps identify cost-effective implementation strategies that maintain product affordability while ensuring profitability

Post-marketing

- **Challenges:** Integrating new therapeutic evidence/medical devices into routine clinical practice, ensuring clinicians and patients follow practice guidelines, enhancing the quality and effectiveness of health services, risk mitigation (aRMMs and REMS)
- IS frameworks identify factors affecting adoption, engage stakeholders, and evaluate implementation strategies to ensure effective integration and their sustainability

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Implementation Science is now recommended per the Guidelines on Good pharmacovigilence practice for Risk Minimisation Measures (Module XVI)

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 July 2024
EMA/204715/2012 Rev 3

Guideline on good pharmacovigilance practices (GVP)
Module XVI – Risk minimisation measures (Rev 3)

Date for coming into effect of first version	1 March 2014
Date for coming into effect of Revision 1	28 April 2014
Date for coming into effect of Revision 2	31 March 2017
Draft Revision 3 finalised by the Agency in collaboration with Member States	18 November 2020
Draft Revision 3 agreed by the EU Network Pharmacovigilance Oversight Group (EU-POG)	7 January 2021
Draft Revision 3 adopted by the EMA Executive Director*	1 February 2021
Release for public consultation	3 February 2021
End of consultation (deadline for comments)	28 April 2021
Revised draft Revision 3 finalised by the Agency in collaboration with Member States	4 July 2024
Revised draft Revision 3 agreed by the EU Network Pharmacovigilance Oversight Group (EU-POG)	22 July 2024
Revised draft Revision 3 adopted by the Executive Director as final**	26 July 2024
Date for coming into effect of Revision 3*	6 August 2024

* The revised final guidance is applicable to new applications for marketing authorisation, new risk minimisation measures and new studies evaluating risk minimisation measures for authorised medicinal products but not immediately applicable to existing risk minimisation measures and ongoing activities regarding risk minimisation measures; however, where existing risk minimisation measures are amended, the revised guidance should be taken into account and applied if this is considered likely to increase the effectiveness of the risk minimisation measure without jeopardising its familiarity for patients and healthcare professionals using the concerned medicinal product.

*Note: Draft Revision 3 released for public consultation versus Revision 2 included the following:

- Changes to XVI.A. to clarify the role of risk minimisation for risk management planning and for the impact on the risk-benefit balance of medicinal products, and the role of effectiveness evaluation of risk minimisation measures, and to delete/merge concepts already included in other sections of the Module;
- Addition of XVI.B.2. to give more guidance about the criteria for applying/requesting additional risk minimisation measures;
- Changes to XVI.B.3.1. with a new classification for educational materials;
- Changes to XVI.B.3.4. regarding the concept of controlled access systems and examples illustrating the requirements;
- Addition of XVI.B.4. to clarify the role of risk communication, dissemination and implementation as a relevant part of any additional risk minimisation activity;

See websites for contact details

European Medicines Agency www.ema.europa.eu
Heads of Medicines Agencies www.hma.eu

The European Medicines Agency is an agency of the European Union

It is recognised that risk minimisation is an evolving area for which new approaches and methods will emerge. Implementing RMM in healthcare for patient safety requires approaches from the implementation sciences as well as engagement across different stakeholders for patient-centred healthcare. As technology advances, the potential of supporting risk minimisation through digital applications may be considered.

Methods for user-testing should build on those established in the areas of e.g. health literacy, risk perception and communication, patient preferences, human factors and implementation sciences. These include testing of draft materials in survey, focus group and scenario-based study designs.

Fictional Case Study: Implementing Zyphorin in Routine Care

1

Pharmaceutical Industry X has developed a new treatment called Zyphorin, that significantly improves patient outcomes for a specific chronic condition.

Prescribing Zyphorin however requires a particular diagnostic test that is not currently available in routine care.

Background

2

Industry X faces the challenge of integrating this diagnostic test into routine clinical practice to ensure that patients who could benefit from Zyphorin are accurately identified and treated.

The diagnostic test requires specialized equipment and training, which are not widely available in most healthcare facilities.

Situation

3

1. Challenge: Ensure the diagnostic test is available in routine care settings
2. Enhance Adoption of Zyphorin: Encourage healthcare providers to adopt the diagnostic test and prescribe Zyphorin.
3. Improve Patient Outcomes: Ensure patients receive timely and accurate diagnoses to benefit from Zyphorin.

Client Objectives

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Pharma Objectives

Implementation Science Summary: Zyphorin Case Study

Patient-Level

Challenges:
- Limited access to facilities offering the diagnostic test or out-of-pocket costs
- Low health literacy about the condition and the need for testing
- Distrust in new medical technologies or pharmaceutical companies

Opportunities:
- Community outreach and education to raise awareness and build trust
- Mobile testing units or telehealth-enabled diagnostics
- Subsidy programs or co-pay assistance for the diagnostic test

Implementation Strategies:
- Awareness campaigns using media, community events, or social media
- Navigation support through patient navigators or case managers
- Mobile or community-based testing units
- Financial assistance programs for patients

Provider-Level

Challenges:
- Lack of awareness or familiarity with the new diagnostic test
- Workflow disruption—adding a new diagnostic step may slow down care delivery
- Skepticism or resistance to adopting new tools without clear evidence or incentives

Opportunities:
- Continuing medical education (CME) programs focused on Zyphorin and its diagnostic
- Integration into electronic health records (EHRs) to prompt test ordering
- Peer learning networks for providers to share experiences and best practices

Implementation Strategies:
- Training and education workshops, online modules, or certification programs
- Clinical decision support tools integrated into EHRs
- Incentive programs for early adopters or high-performing clinics

System-Level

Challenges:
- Lack of infrastructure for the diagnostic test
- Limited funding for acquiring and maintaining specialized diagnostic tools
- Fragmented healthcare systems that complicate coordination and scale-up
- Reimbursement uncertainty for the diagnostic test

Opportunities:
- Public-private partnerships to fund and distribute diagnostic equipment
- Policy advocacy to include the test in national screening or treatment guidelines
- Pilot programs in high-need areas to demonstrate feasibility and impact

Implementation Strategies:
- Infrastructure investment through partnerships with health systems or governments
- Supply chain coordination for timely distribution of diagnostic kits

Thank you!

Overview of theories, models, and frameworks in implementation science

Bridget Gaglio, PhD, MPH

Thermo Fisher Scientific, Waltham, MA, USA

Presented at the International Society for Pharmacoeconomics and Outcomes Research, Inc (ISPOR) Meeting; May 13–16, 2025; Montreal, CA/Virtual

The world leader in serving science

Learning objectives

1. Understand what implementation science theories, models, and frameworks are and why they matter in industry-sponsored research

2. Become familiar with three widely used implementation science theories, models, and frameworks

3. Application to case study

Introduction to Implementation Science Theories, Models, and Frameworks

Definitions

Theories: Provide a framework for understanding the **causal mechanisms** of implementation and **predicting** how factors influence outcomes, according to implementation science

Models: **Describe** and/or **guide the process** of translating research into practice, offering a simplified **representation** of the implementation journey

Frameworks: **Describe** the **factors** that **influence** implementation outcomes, providing a **structured way** to analyze and address potential barriers and facilitators

Why use TMFs in IS research?

01 Provide a structured approach throughout aims, methods, measures, and evaluation

02 Improve understanding of context and mechanisms (How? Why?)

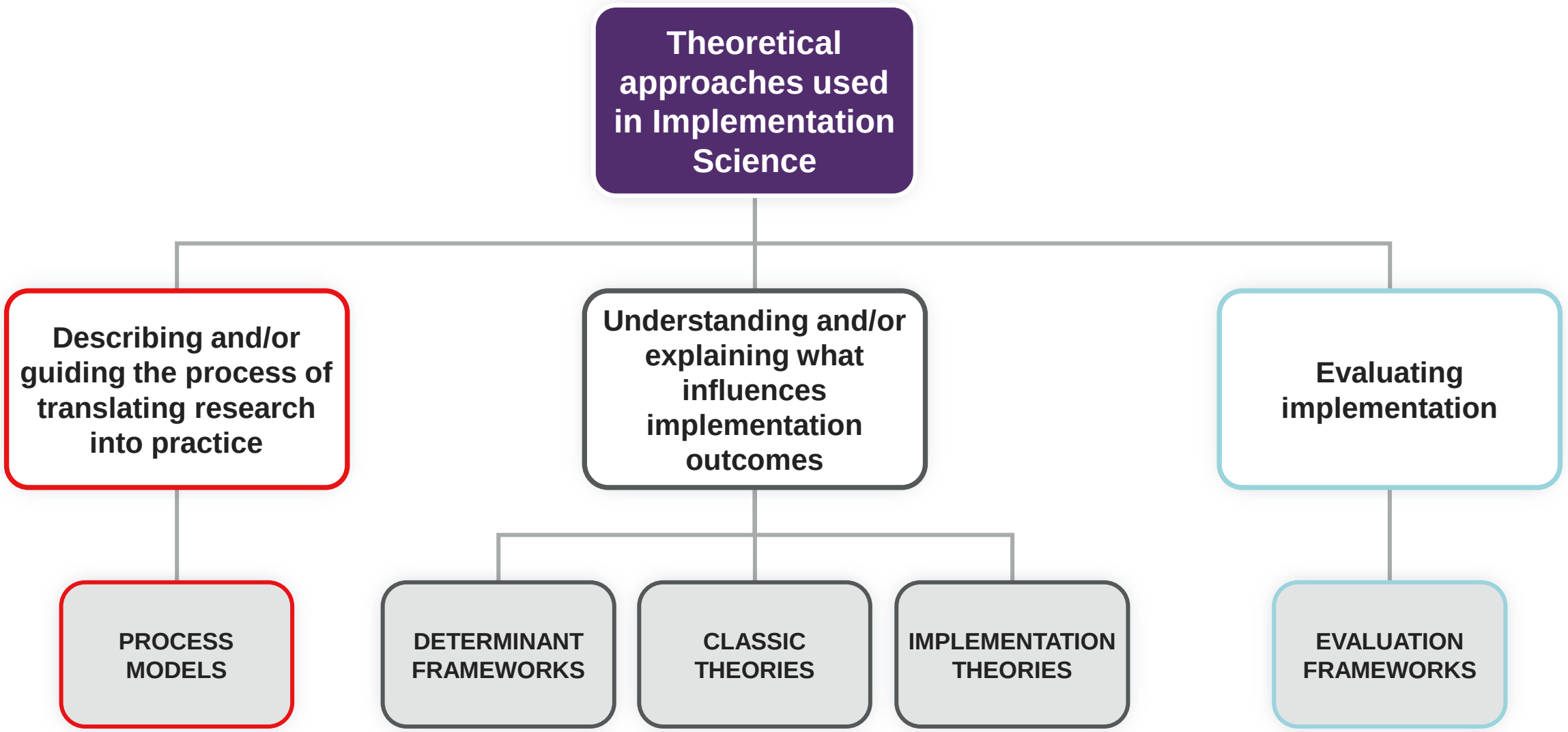
03 Enhance and inform planning of the study as well as dissemination/scale-up

04 Increases replication (in terms of shared processes, outcomes, and terminology)

05 Potential to enhance generalizability

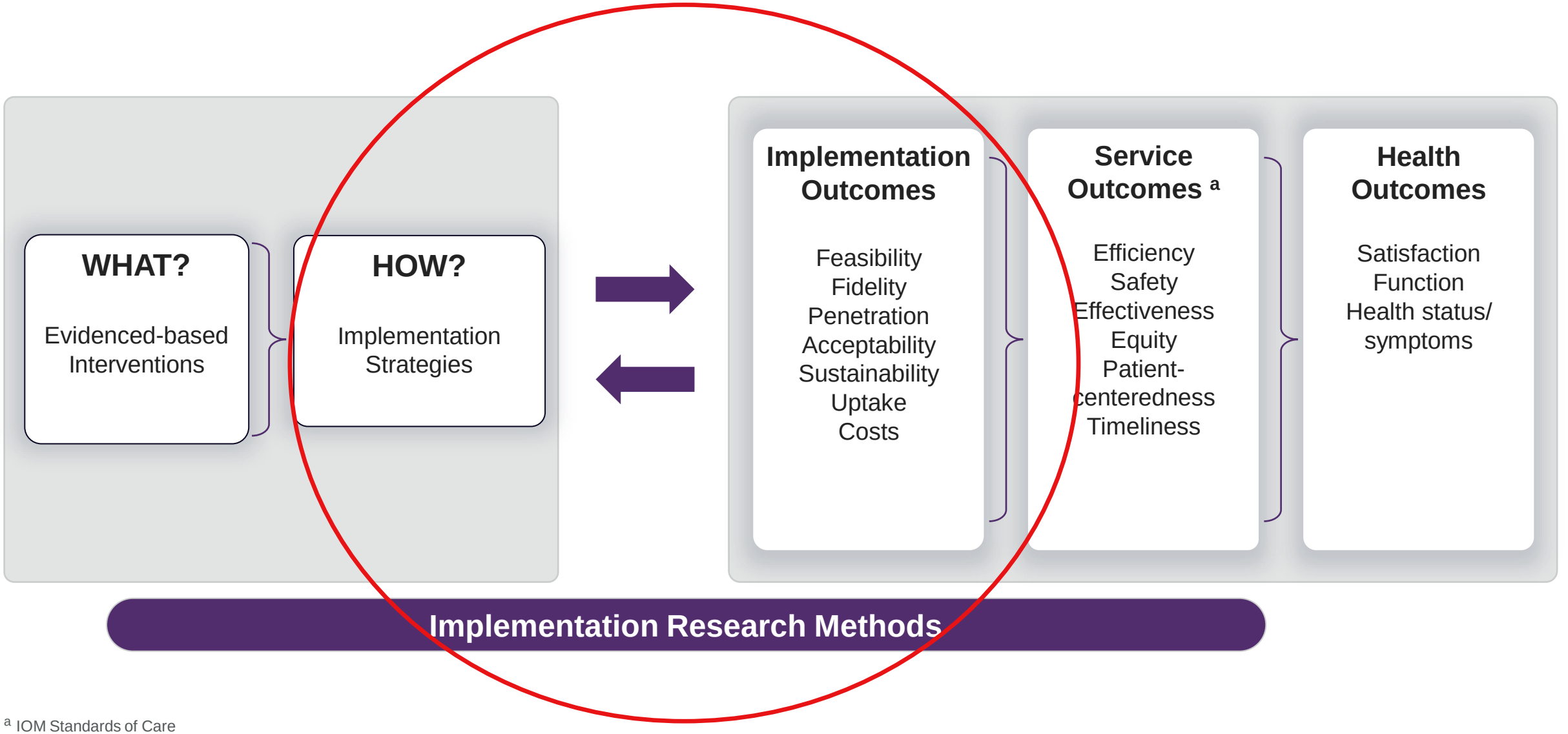
Abbreviations: IS = implementation science; TMF = theories, models, and frameworks

Choosing a TFM: theoretical approaches and categories



Adapted from: Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.* 2015;10(1):1-13.

Outcomes for implementation research[1]



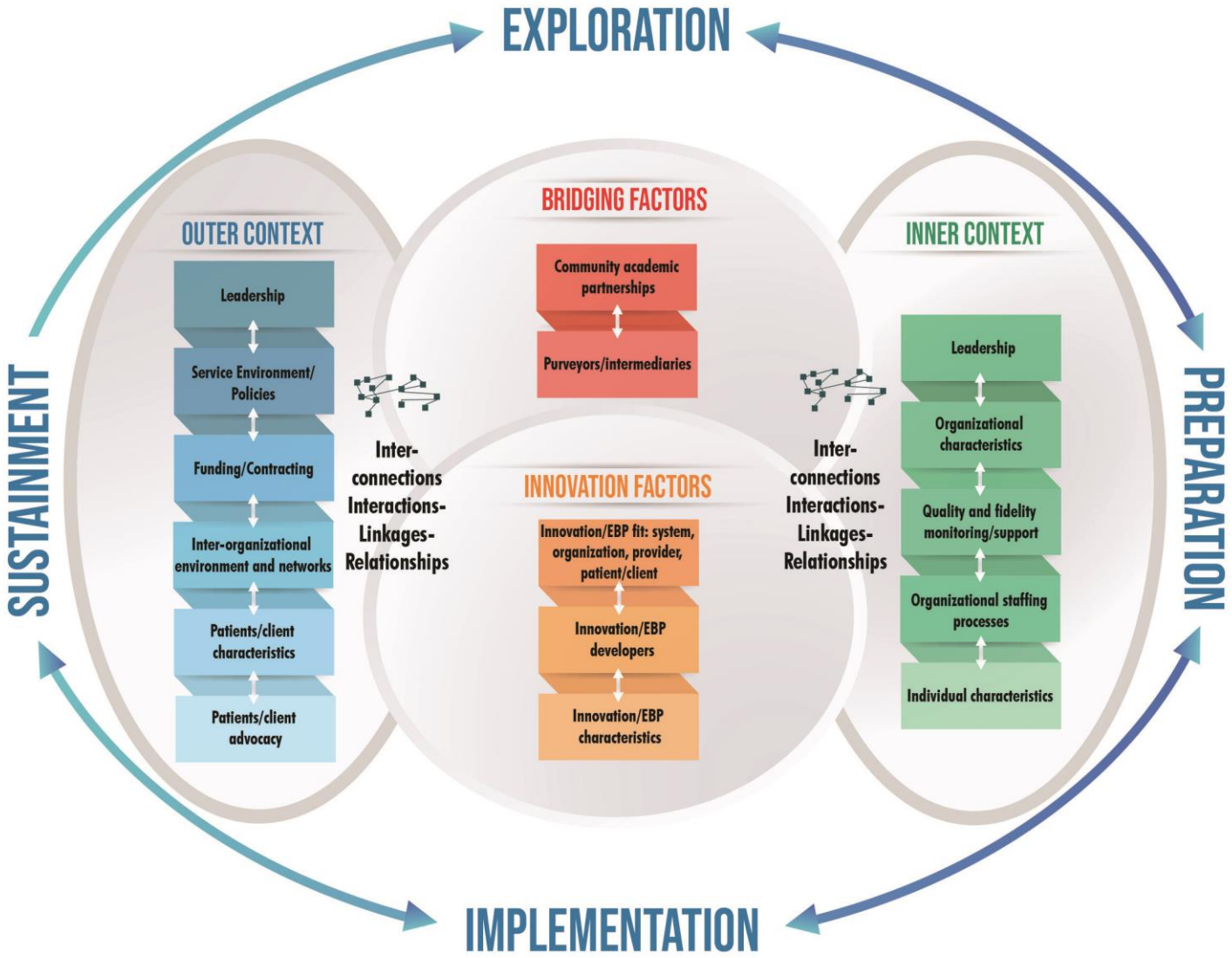
[a] IOM Standards of Care

Reference: 1. Proctor E, Silmere H, Raghavan R, et al. Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. *Admin Policy Ment Health*. 2010. 38(2):65-76.

TMF Examples

Exploration, Preparation, Implementation, Sustainment (EPIS) model

- Example of a **process** model
- This model helps map where you are in the process and what matters most at each phase

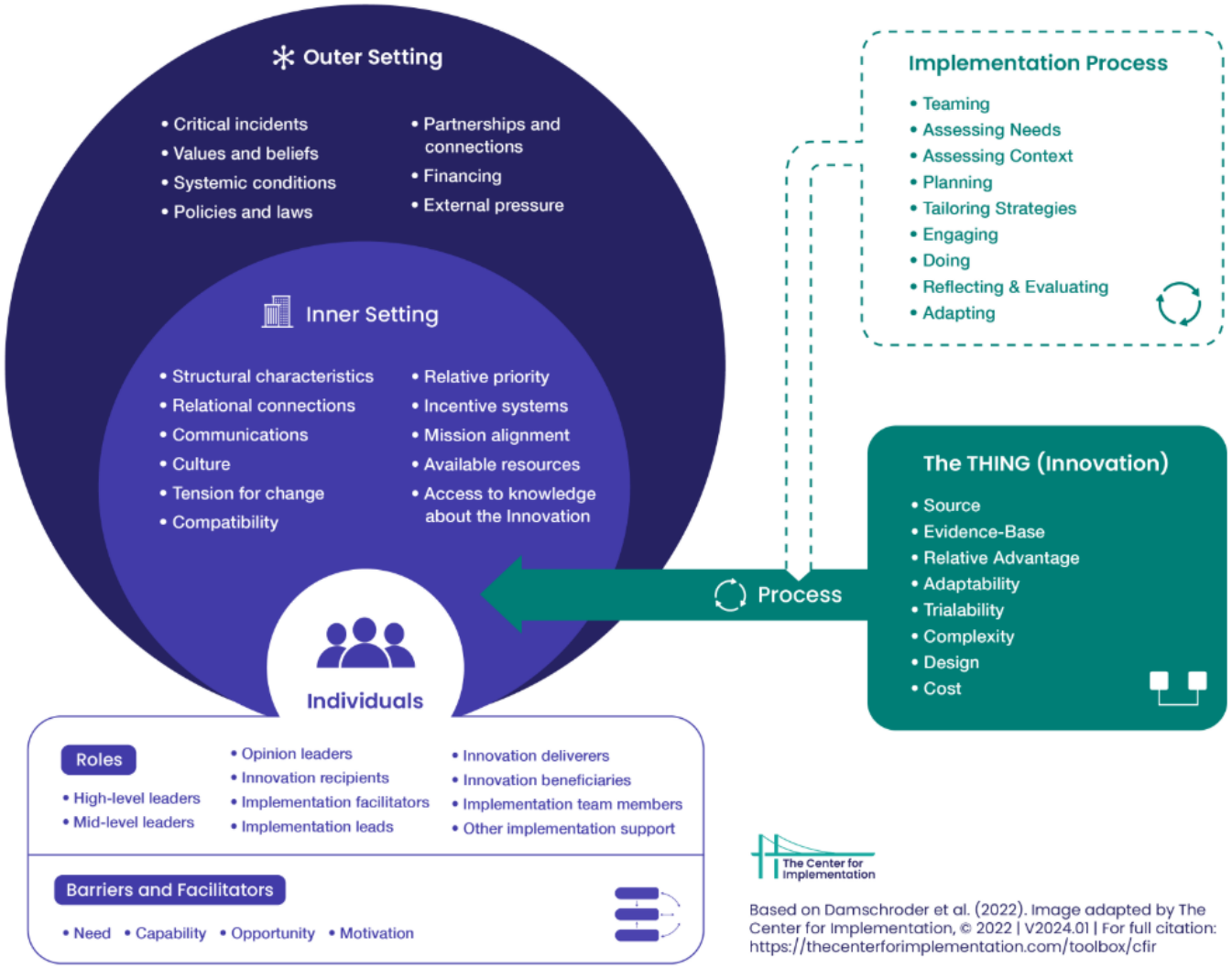


Reference: Aarons GA, Hurlburt M, Horwitz SM. Advancing a conceptual model of evidence-based practice implementation in public service sectors. *Adm Policy Ment Health*. 2010. 38(1):4-23.

Consolidated Framework for Implementation Research (CFIR)

- Example of a **determinant** framework
- CFIR helps identify what factors influence successful implementation by offering a structured list of things to consider across different settings

Consolidated framework for CFIR 2.0



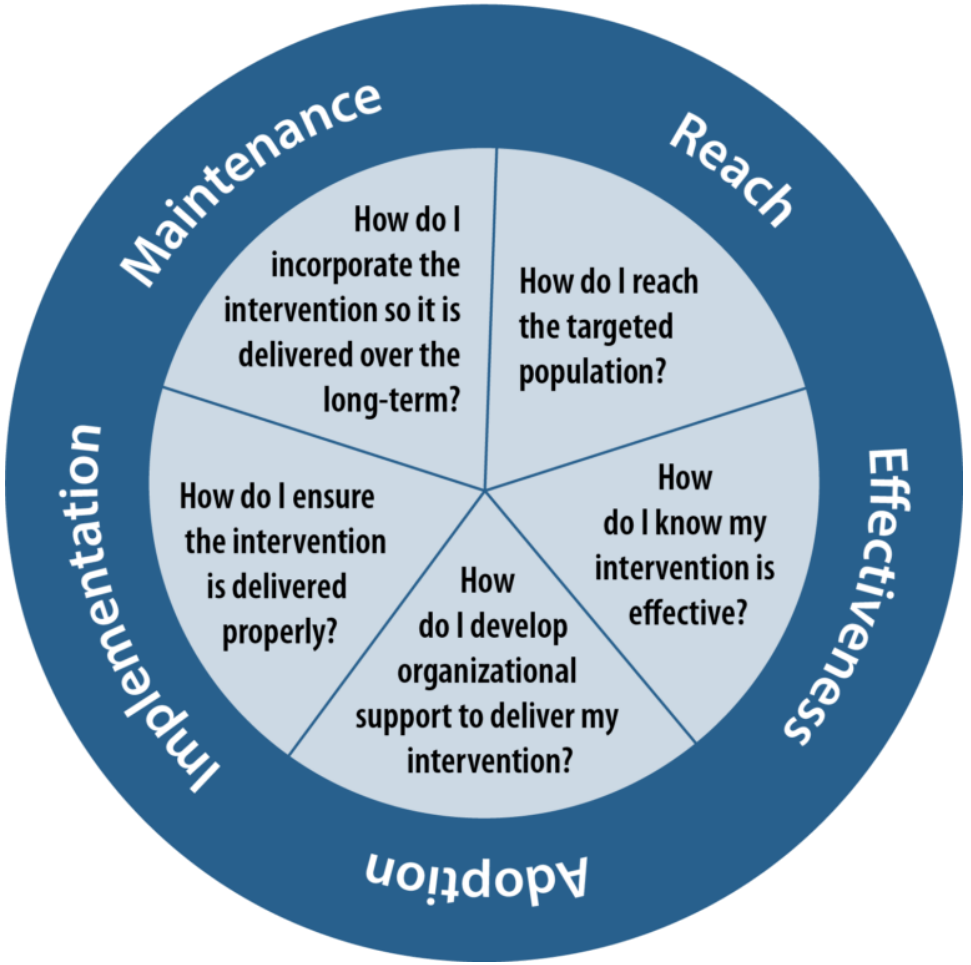
Based on Damschroder et al. (2022). Image adapted by The Center for Implementation, © 2022 | V2024.01 | For full citation: https://thecenterforimplementation.com/toolbox/cfir

Reference: Damschroder LJ, Reardon CM, et al. The updated Consolidated Framew for Implementation Research based on user feedback. Imp Sci. 2022.17(1):75.

Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework

- Example of an **evaluation** framework
- Focus is on external validity – how well an intervention works in the real world
- Focus is also on how widely and how sustainably it worked

Elements of the RE-AIM framework



Reference: Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. 1999. 89(9):1322-1327.

TMF take-aways

01 TMFs serve as a guide

02 No single TMF is “best” or “right”

- Choice should be determined by informing the study from the outset
- Should align with aims, study design, data collection instruments, analyses, and reporting

03 Many TMFs are available. Your study may require more than one

- Test, refine, and adapt

Tools and Resources: TMF Selection Resources: TMF selection

- Web-based tools:
  - Dissemination Implementation – An interactive webtool to help you use D&I models
  - T-CaST_researchers.pdf
  - T-CaST_practitioners.pdf
  - Resources and Tools – RE-AIM
  - Tools – The Consolidated Framework for Implementation Research

- Articles:
  - Tabak RG, Khoong EC, Chambers D, Brownson RC. Bridging research and practice: Models for dissemination and implementation research. *Am J Prev Med*. 2012. 43(3):337-350.
  - Nilsen P. Making sense of implementation theories, models, and frameworks. *Implementation Science*. 2015. 10:53.

Application to Case Study

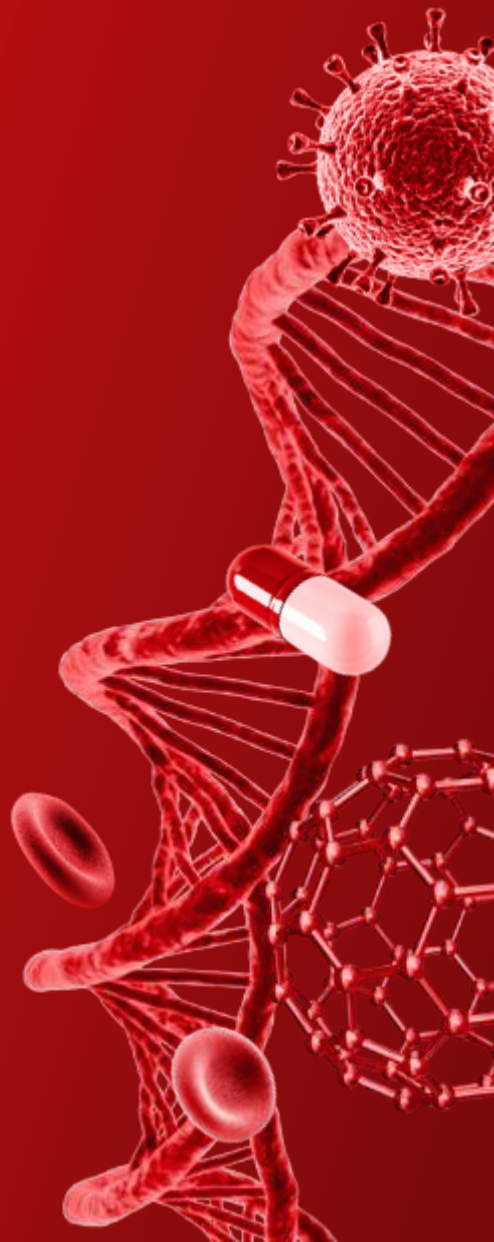
- How would you go about selecting a TMF(s) to guide your work? What should you consider?
  - Characteristics of the investigator/study team who will use the TMF
    - Attitudes towards staying true to the TMF
  - Knowledge about TMFs
    - Preference / Training
  - Characteristics of the TMF
    - Ease of use / understanding
    - Fit to your study

- How does the TMF you selected bring a structured approach to your study?
  - Understanding
  - Guiding
  - Evaluation

Disclosures

- Bridget Gaglio is an employee of PPD™ Evidera™ Patient-Centered Research, Thermo Fisher Scientific and a consultancy that provides scientific consulting services to pharmaceutical companies. The development of this presentation was funded by Thermo Fisher Scientific. All views are those of the author.
- Editorial and graphic design support were provided by Karissa Calara and Kawthar Nakayima of Thermo Fisher Scientific

Thank you



Unlocking Impact: Accelerating the pharma pipeline with Implementation Science

Mahrukh Zahid
Director, Implementation Science

NOVARTIS | Reimagining Medicine

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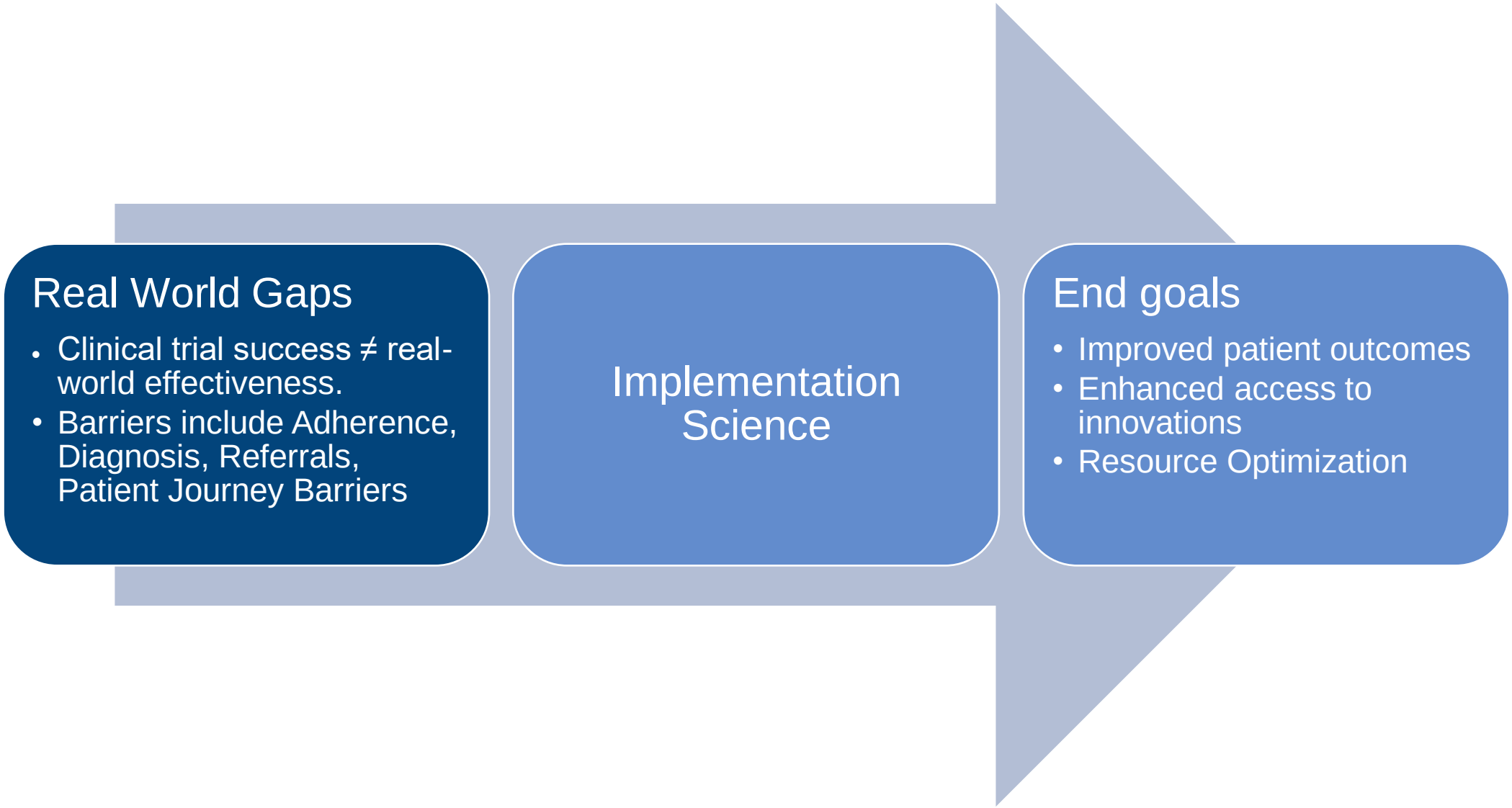
Current Challenges



How Implementation Science can add value

Implementation Science can help pharma understand where, why, and how products fail to translate into everyday care and put strategies in place to overcome these barriers in advance

1. Improves Patient Outcomes – Ensures treatments and interventions are successfully adopted in Healthcare Systems.
2. Enhances Access – Identifies and removes adoption barriers for our innovations.
3. Optimizes Resource Allocation – Identifies evidence-based and effective strategies to address adoption barriers.
4. Strengthens Existing Initiatives– Provides a systematic lens on tackling clinical adoption while leveraging existing efforts.

Achieving the Triple Win using Implementation Science

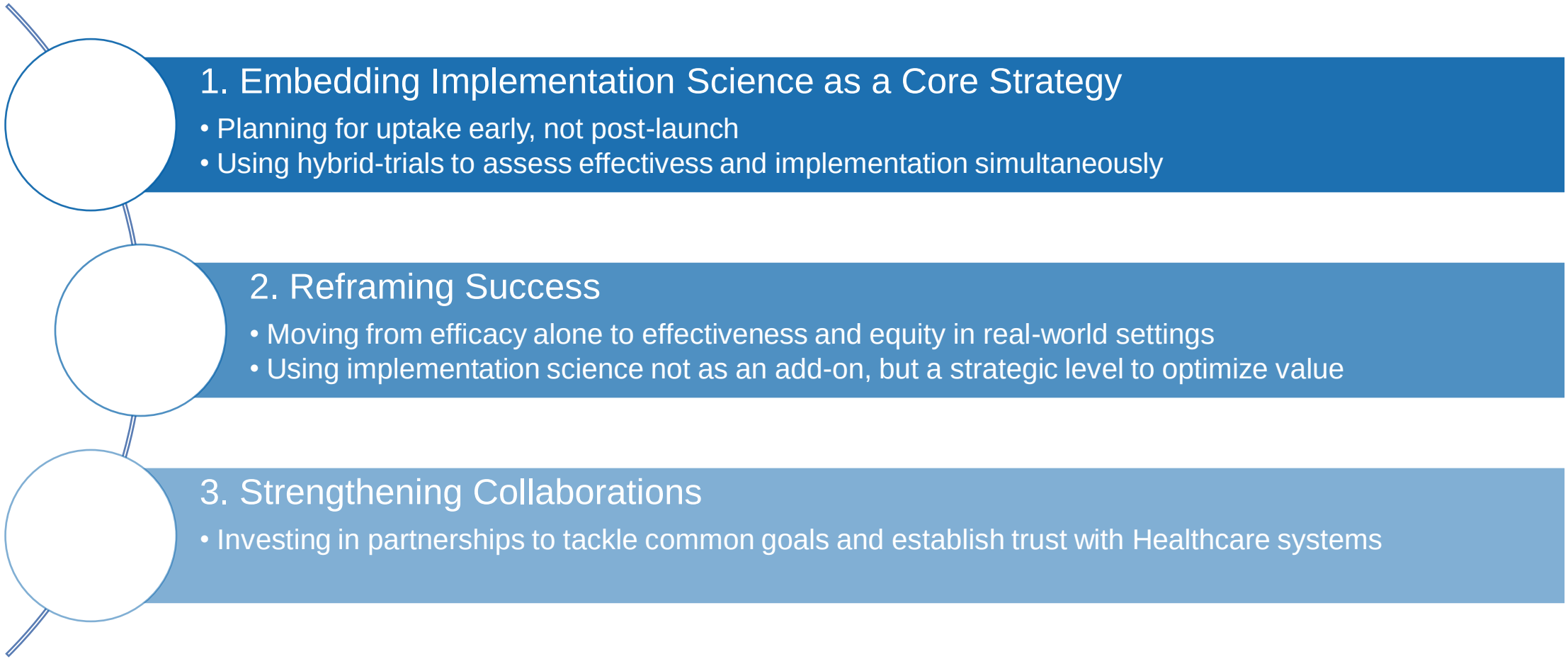
Acheiving the Triple Win:

By using a discipline that studies how to promote effective adoption, we can help

Patients: Faster & equitable access, improved outcomes and adherence.	**Healthcare Systems**: Scalable and sustainable integration of new evidence-based practices	**Pharma**: Increased product value and real-world success.

Olson MS, Zullig LL, Geest S. How pharma can amplify product value with implementation science. J Comp Eff Res. 2024 Oct;13(10)

Setting up for success with Implementation Science



Case study - HELyx-1

Hidradenitis Suppurativa

Example - HELyx-1 study

A Non-interventional, prospective implementation science study aiming to increase diagnosis rate and accelerate referrals for patients with Hidradenitis suppurativa (HS)

Key challenges

- Low awareness of HS
- Delayed diagnosis and meandering patient journey
- Limited access to adequate therapy

Objectives

- **Increase diagnostic screening**
- **Accelerate and increase the diagnostic detection rate** of patients with HS across medical specialties
- **Broaden objective assessments of HS symptoms** and disease severity into clinical practice
- **Accelerate referral of HS patients** to physicians experienced with HS

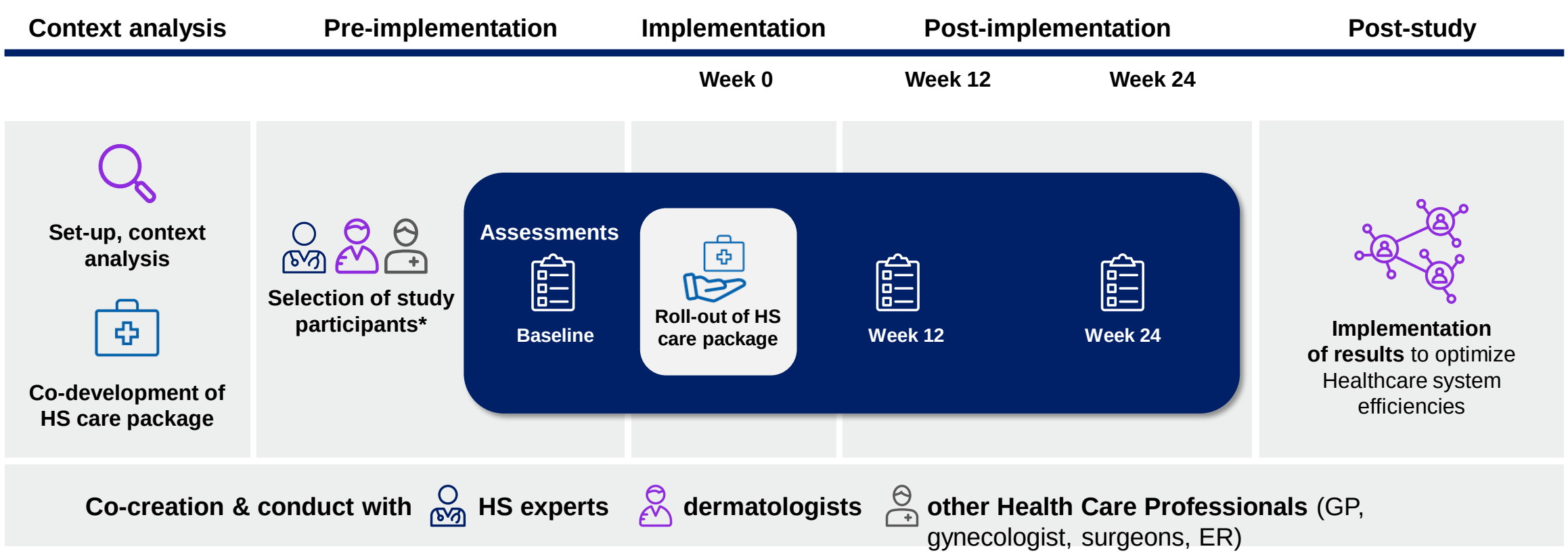
Project

Implementation science study using the Consolidate Framework for Implementation Research (CFIR)

- Build on and support local **Health Care Professional networks**
- Co-create **HS care package** with Key Opinion Leaders
- Measure impact of the implementation

HELyx-1 study design

Focusing on local context in pilot country Germany



*dermatologists, GPs, gynecologists, surgeons

ER, emergency room unit; GP, general practitioner, HS, hidradenitis suppurativa.

HELyx-1 expected impact

- Transform clinical practice by identifying barriers to diagnosis and treatment
- Strong partnerships with Health Care Professionals creating enduring HS networks
- Effective implementable solutions that can be scaled for Health Care Professionals
- Optimize health care systems efficiencies

Reflection

What are your reflections on the hypothetical and real-life case studies?

How can Implementation Science optimize your work in reaching similar objectives to reduce barriers to access to innovations?

Wrap-up and follow up questions

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