Implementation science:
Making research findings more powerful for use in clinical practice

Sabina De Geest, University of Basel (CH) & KU Leuven (B)

The "leaky" research pipeline

Research waste 1

Chalmers & Glasziou Lancet 2009;374:86-9

>50% designed without reference to systematic reviews of existing evidence

>50% has avoidable research flaws / biases

50% of research is never published in full

50% is unusable or incompletely reported or both

Research waste 2

Balas & Boren. Yearbook Med Inform. 2000;1:65–70

% sustainability?

As little as 14% of evidence is ever implemented

Implementation science

It takes a mean of 17 years to get research evidence implemented

Implementation science:

Bridging the gap between trial and real world settings to implement and sustain evidence based interventions

Definition Implementation science

- A commonly used definition:
  - "The scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care"

Eccles & Mitmann. Implement. Sci. 2006; 1:1

Tower of Babel
Variation and inconsistency in terminology ➔ confusion

- US
  - Dissemination & implementation science, research utilization

- Canada
  - Improvement science, knowledge utilization, knowledge translation

- UK
  - Evidence based medecine, diffusion of innovations, technology transfer

- Australia
  - **Know-do gap**

…and many more

US National Libary of Medicine:
1 January 2019

Implementation science
introduced as MeSH term (PubMed)

McKibbon et al.Implementtion Science 2010; 5:16; Estabrooks et al. Nurs Res. 2004; 53-293-303: Mitchell et al. J. Oncol Pract. 2017: 13:523-529; Addie et al. Applying an Implementation Science Approach to Genomic Medicine: Workshop Summary/ National Academies for Science, Medicine and Engineering 2016; ISBN 978-0-309-43776-9

When defining implementation science, some very non-scientific language can be helpful…

- The intervention/practice/innovation is **THE THING**

- *Effectiveness* research looks at whether **THE THING** works

- *Implementation* research looks at how best to help people/place **DO THE THING**

- Implementation strategies are **the** <u>**Stuff**</u> we do to try to help people/places **DO THE THING**

- Main implementation outcomes are **HOW MUCH** and **HOW WELL** they **DO THE THING**

Curran <u>Implementation Science Communications</u> 2020; 1:0

Intervention

Implementation strategies
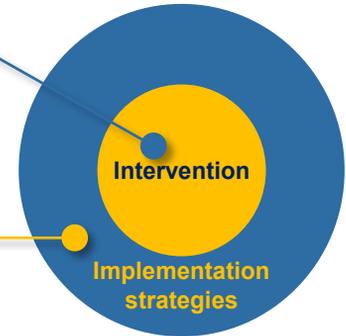
Towards powerful real-world translation

- **"Trial-world"**
  - **"Could it work?"**
  - RCT
  - Efficacy
  - Null hypothesis
  - Keep things clear

- **"Real-world"**
  - **"Does it work and when?"**
  - Pragmatic trials - pRCT
  - Effectiveness
  - Alternate hypothesis
  - Live with complexity

- **"Daily clinical practice"**
  - **"Making it work"!**
  - Impact (implementation & sustainability)
  - Hybrid designs and other IS specific designs
  - "How do we get evidence to drive practice?"
  - Embrace complexity
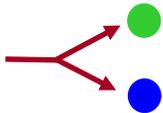
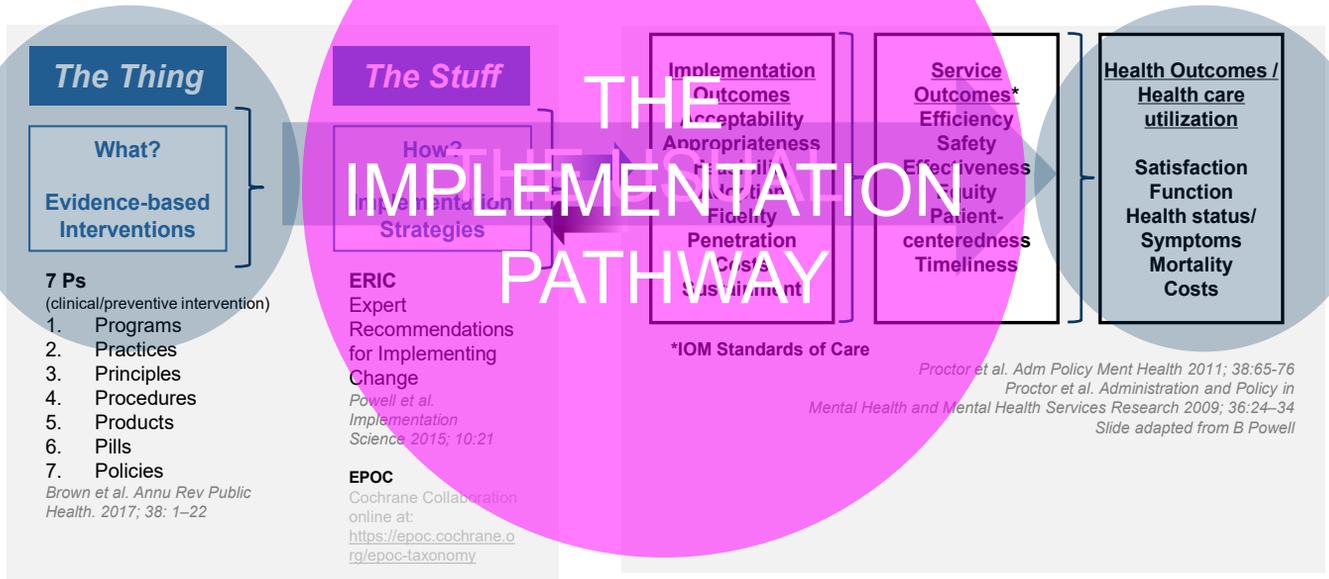**Intervention → Outcome
Differential**


**Intervention → Outcome
Pattern Recognition**

**EBP → Implementation & effectiveness
outcomes
How and why does it work
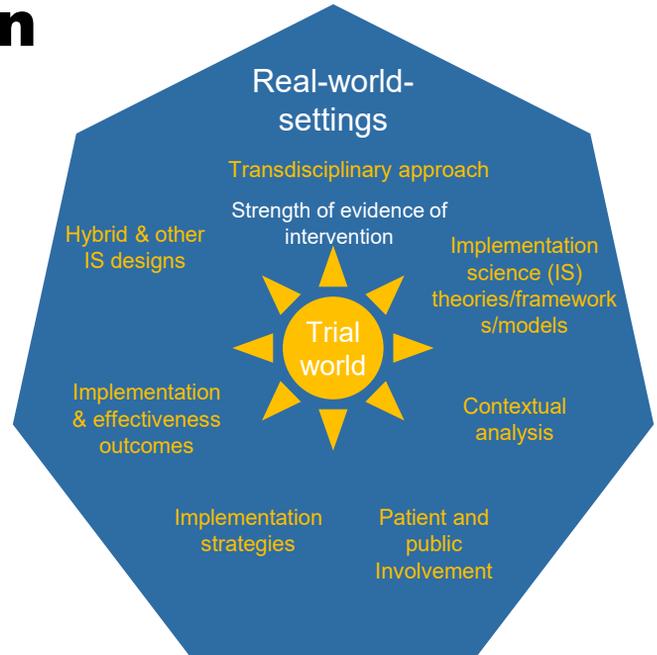and is it *sustained* in variable contexts?**

Adapted from Abraham I, University of Arizona

Positioning the implementation pathway

The Thing

What?

Evidence-based Interventions

7 Ps
(clinical/preventive intervention)
1. Programs
2. Practices
3. Principles
4. Procedures
5. Products
6. Pills
7. Policies

Brown et al. Annu Rev Public Health. 2017; 38: 1–22

The Stuff

How?

Implementation Strategies

ERIC
Expert Recommendations for Implementing Change
Powell et al. Implementation Science 2015; 10:21

EPOC
Cochrane Collaboration online at: https://epoc.cochrane.org/epoc-taxonomy

THE IMPLEMENTATION PATHWAY

THE INSTALL

Implementation Outcomes
Acceptability
Appropriateness
Feasibility
Adoption
Fidelity
Penetration
Costs
Sustainment

Service Outcomes*
Efficiency
Safety
Effectiveness
Equity
Patient-centeredness
Timeliness

*IOM Standards of Care

Health Outcomes / Health care utilization

Satisfaction
Function
Health status/ Symptoms
Mortality
Costs

*Proctor et al. Adm Policy Ment Health 2011; 38:65-76
Proctor et al. Administration and Policy in Mental Health and Mental Health Services Research 2009; 36:24–34
Slide adapted from B Powell*

Implementation science applies a variety of methods and strategies for powerful real-world translation
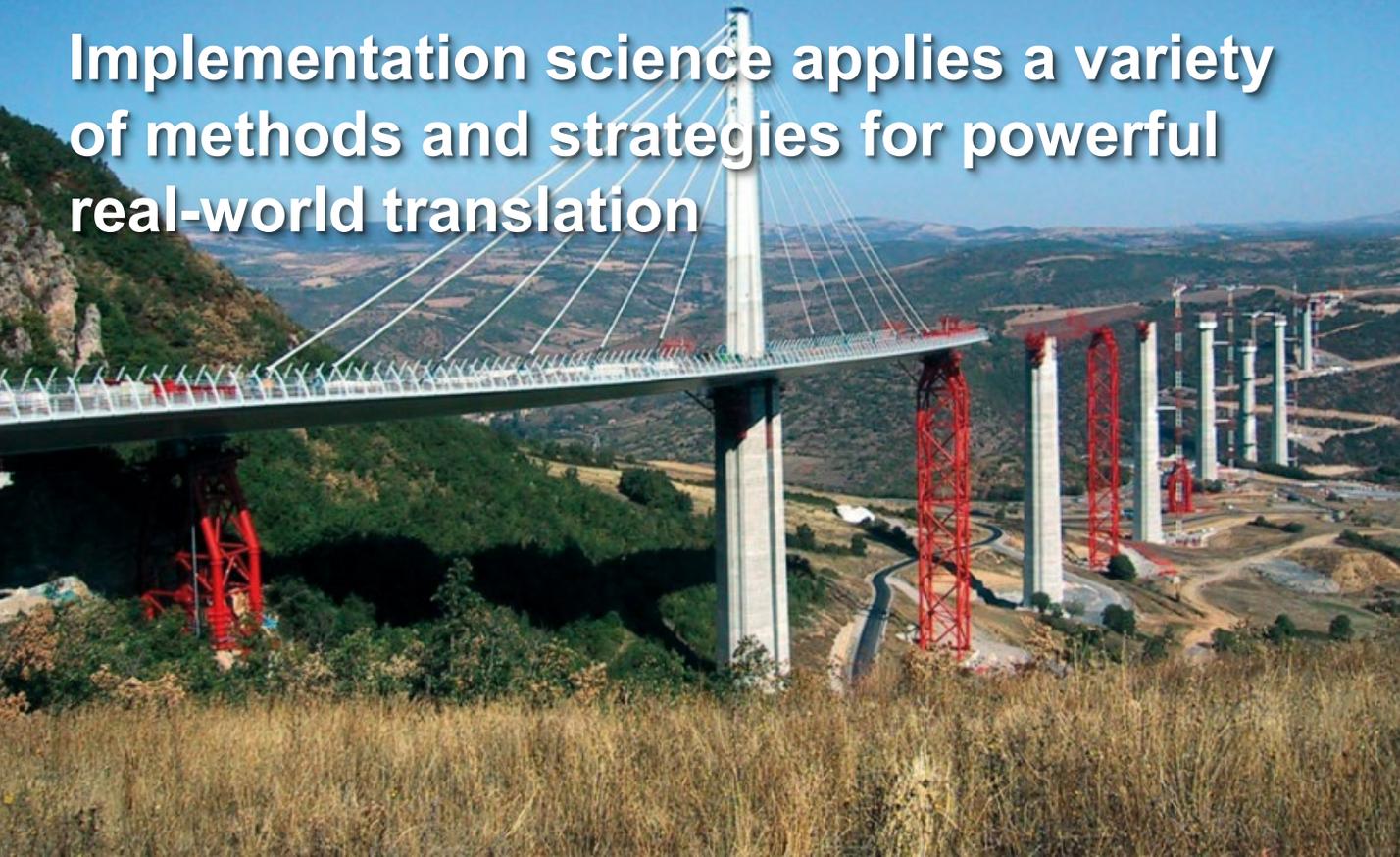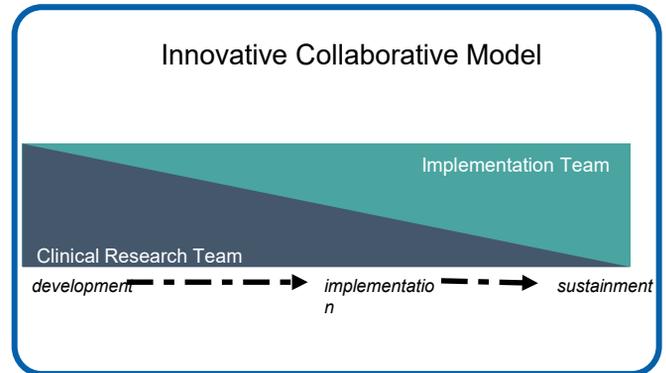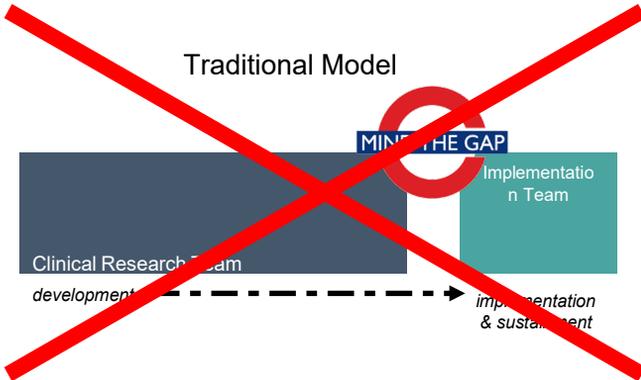
The Basel Heptagon of Implementation Science

- Key elements of implementation science to successfully cross from the trial world to real world settings

Integrating the Implementation Science Team over the Lifecycle of an Intervention

Traditional Model

MIND THE GAP

Implementation Team

Clinical Research Team

development ➔ implementation & sustainment

Innovative Collaborative Model

Implementation Team

Clinical Research Team

development ➔ implementation ➔ sustainment

Zullig et al. Manuscript in preparation

Implementation science:
An example

Trial world - Best Evidence

Real world settings

Implementation Science

GAP

Towards implementation of an Integrated Model of Care in Allogeneic Hematopoietic SteM Cell TransplantatIon faciLitated by eHealth Technology: The SMILe project
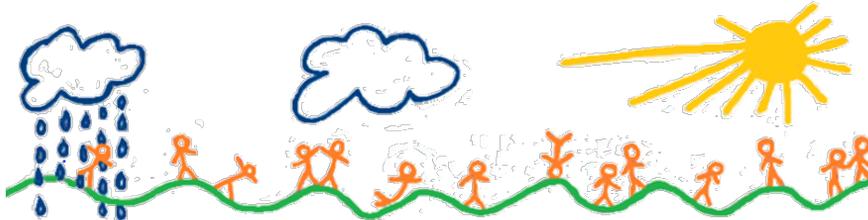
Need for innovation in follow-up care of stem cell transplant patients:
# Basis of SMILe project

- Increasing numbers of long-term survivors after allogeneic stem cell transplantations (alloSCT)[1,2]
- Frequent re-hospitalizations partially avoidable
- 70%-90% of the long-term survivors develop chronic conditions, increasing demand on Tx-Centers [3]
- Early detection of health deterioration & self-management support with behavioral and psychosocial aspects [4,5]
- eHealth solutions show promise in improving clinical outcomes [6,7]
- No integrated (eHealth supported) integrated care model for alloSCT patients so far.

1. Passweg et al. BMT;2019; *2.* Majhail NS, Rizzo JD. BMT; 2013;48(9):1145-51; *3.* Bevans et al. Biol Blood Marrow Transplant. 2016. *4.* Kirsch et al. BMT; 2014;49(9):1223-30.; *5.* Syrjala et al.; JCO. 2012;30(30):3746-51.; *6.*Schmid et al. Am J.Transplant . 2017;17(6):1594-605., *7.* Basch et al. JCO. 2015:630830

The Basel Heptagon of Implementation Science

- Key elements of implementation science to successfully cross from the trial world to real world settings
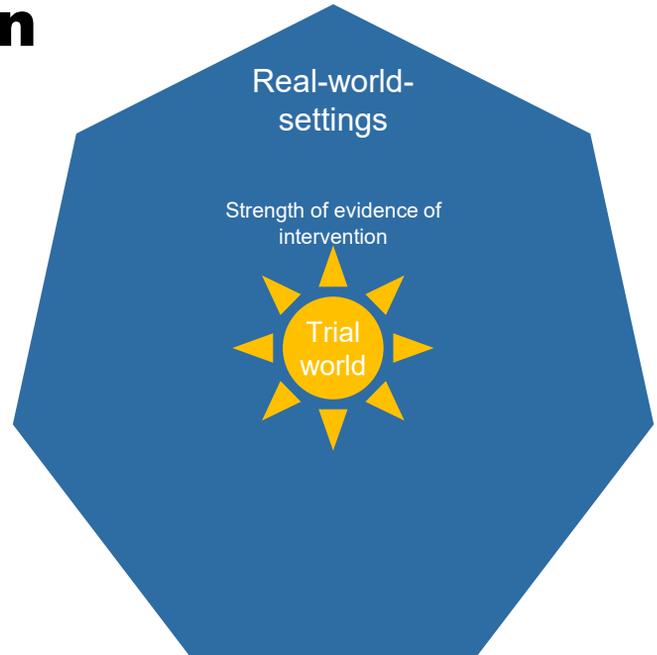
De Geest et al.
Swiss Medical Weekly 2020;
150:w20323; doi:10.4414/smw.2020.20323

Strong evidence from the trial world for eHealth facilitated integrated models of care to improve outcomes

Chronically ill populations	Cancer & solid organ TX

Chronically ill populations

↑ Biomedical, behavioral and psychosocial outcomes e.g [1-4]
  – ↓ all cause mortality
  – ↑ patient engagement
  – ↑ Qualtity of life

– ↓ utilization of health care [1]

Cancer & solid organ TX

↑ Survival [5]
↑ QoL [5]
↓ Symptomburden e.g. fatigue [6]
↓ Emergency room visits [5, 7,8]
↓ Re-hospitalization [7]

+ Case-Management ↑ effective [9]

1. Widmer, R. J., et al. (2015). Mayo Clin Proc.; 2. Elbert, N. J et al. (2014). JMIR; 3. Kuijpers, W., et al. (2013). JMIR.; 4. Barello, S., et al. (2016). Frontiers in psychology. 5. Basch, E., et al. (2017). Jama.; 6. Kearney, N., et al. (2009). Support Care Cancer; 7. Kaier, K., et al. (2017). Health Economics Review; 8. Schmid, A., et al. (2017). American Journal of Transplantation. ; 9. Mooney, K. H., et al. (2017). Cancer Med.

Aims SMILe study

1. **To identify** unmet needs, practice patterns and relevant context characteristics of alloSCT follow-up care in Switzerland, focusing particularly on chronic illness management and **to assess technology openness** of alloSCT patients and clinicians.

2. **To develop** the SMILe eHealth facilitated integrated care model (SMILe-ICM) and to determine contextually adapted **implementation strategies**

Dual aims of SMILe:
effectiveness & implementation

3. **To evaluate** *effectiveness outcomes* **of the SMILe-ICM** in view of re-hospitalization rate, (primary outcome), total healthcare utilization costs, medication non-adherence, treatment burden, health-related quality of life (HRQL), quality-adjusted life year (QALY), acute and chronic GvHD incidence and grade and overall survival rate (secondary outcomes) in the first year post-alloSCT.

4. **To evaluate** *the implementation* **of the SMILe-ICM** regarding feasibility, acceptability, appropriateness, and fidelity (implementation outcomes) and **to evaluate the implementation pathway** from patients and health care professionals perspective.
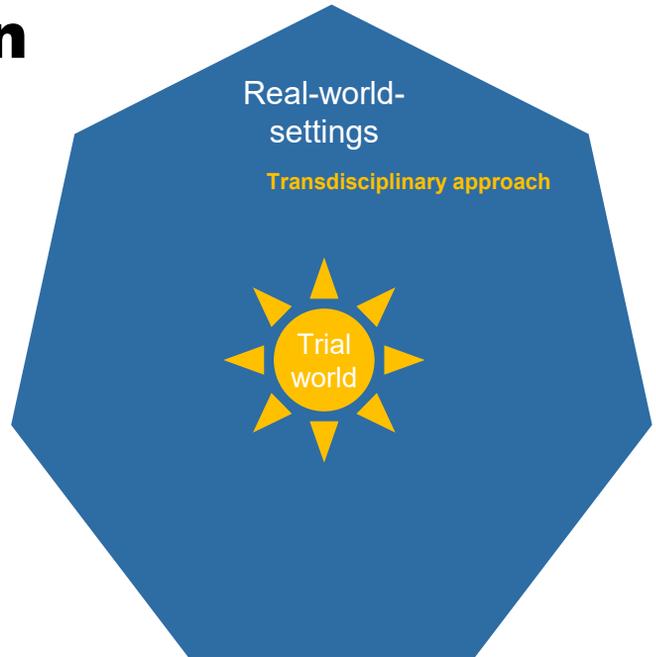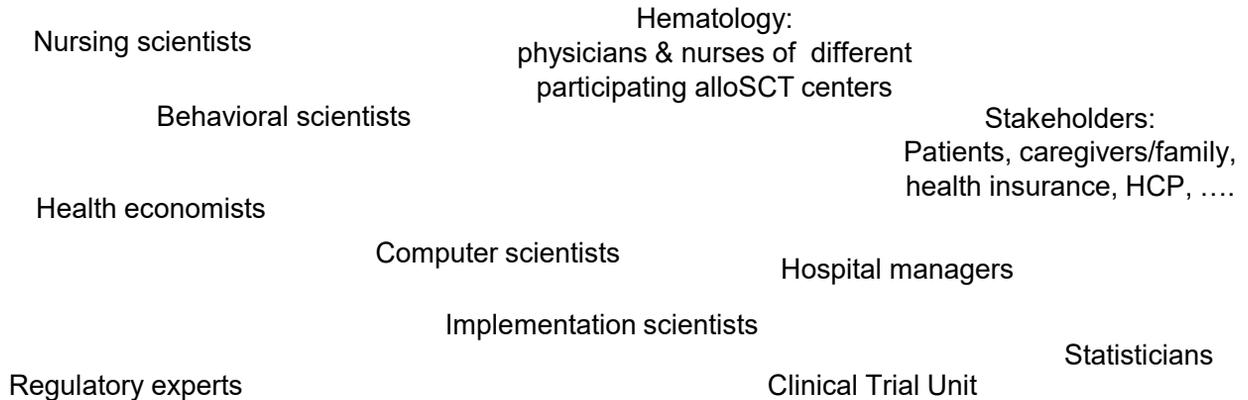
SMILe Project – overview
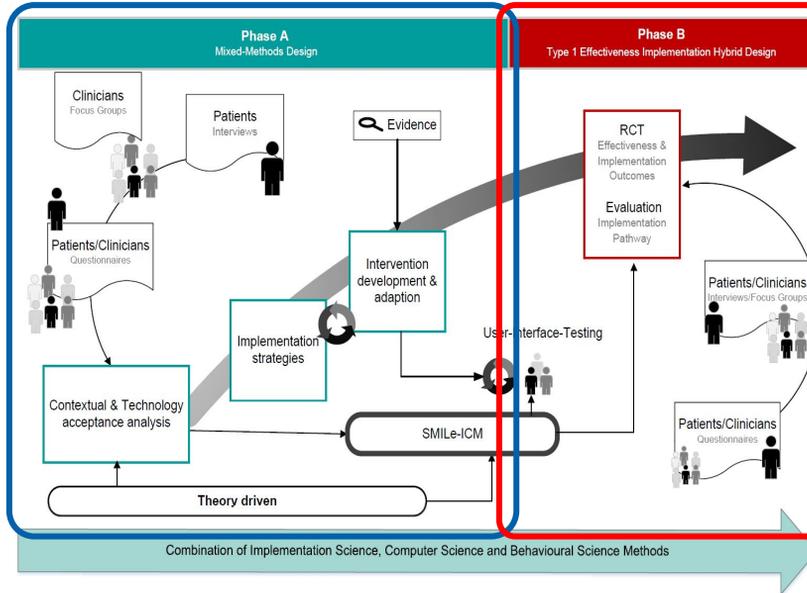
The Basel Heptagon of Implementation Science

- Key elements of implementation science to successfully cross from the trial world to real world settings
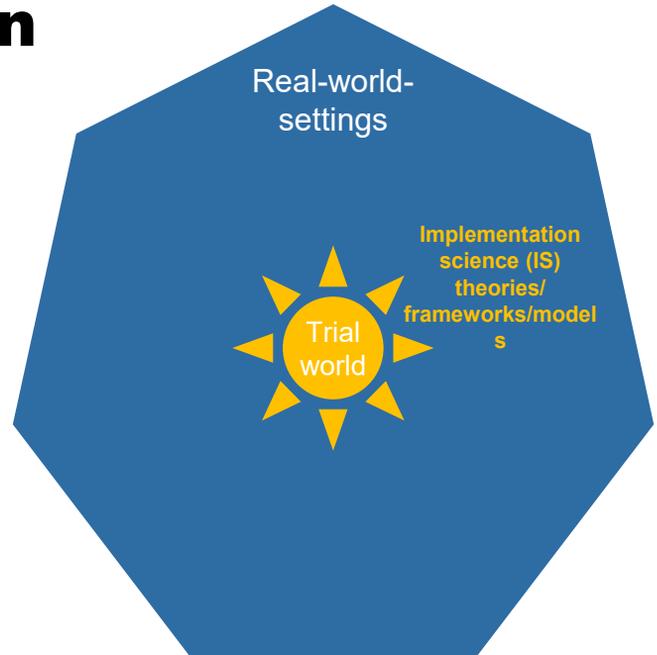
Real-world-settings

Transdisciplinary approach

Trial world

SMILe: Transdisciplinary team combining expertise from many fields from the start (cross-functional collaboration)

Nursing scientists

Behavioral scientists

Health economists

Regulatory experts

Hematology:
physicians & nurses of different
participating alloSCT centers

Stakeholders:
Patients, caregivers/family,
health insurance, HCP, ….

Computer scientists

Hospital managers

Implementation scientists
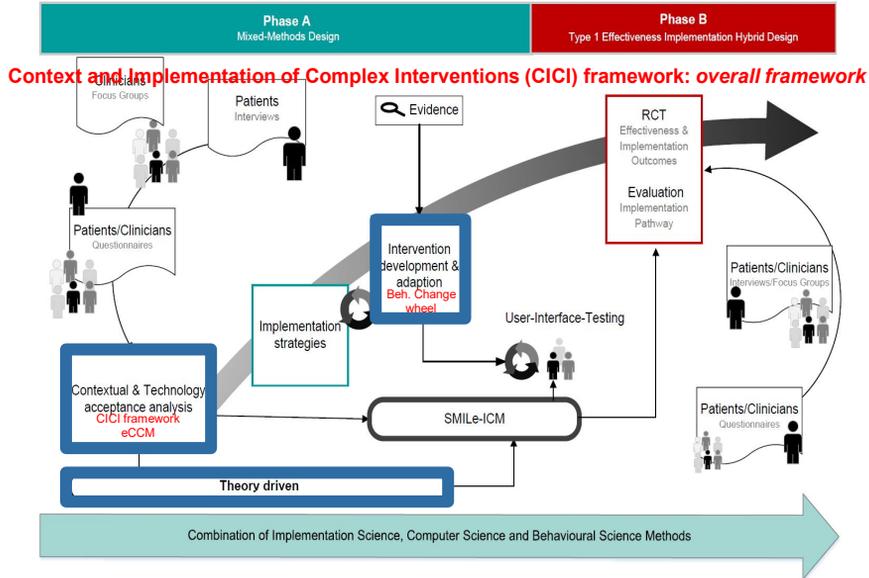
Statisticians

Clinical Trial Unit

The Basel Heptagon of Implementation Science

- Key elements of implementation science to successfully cross from the trial world to real world settings
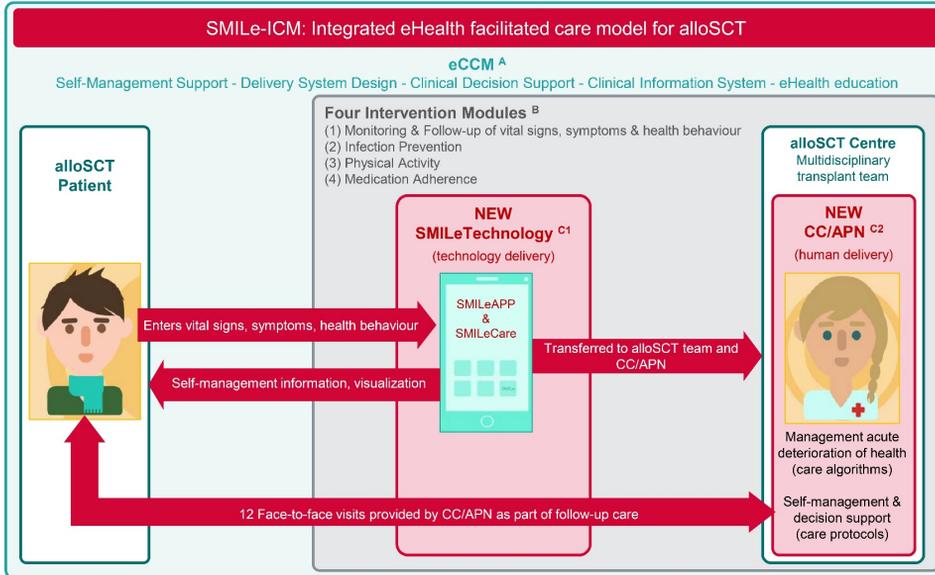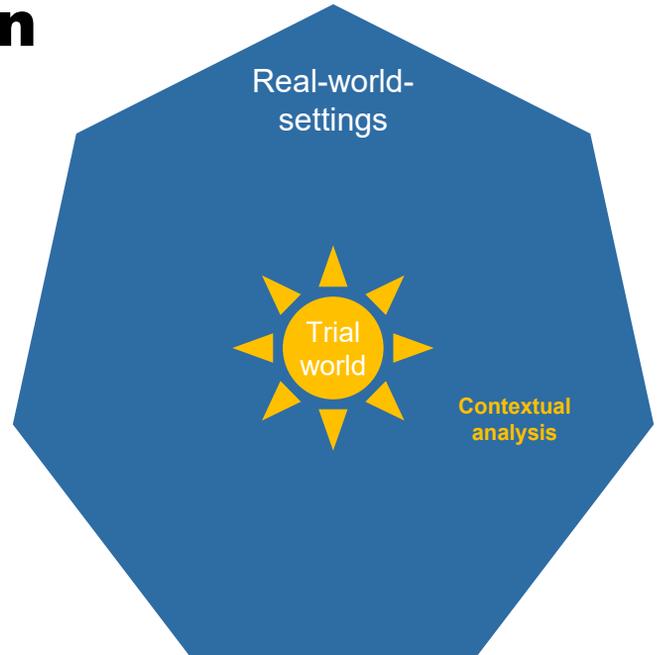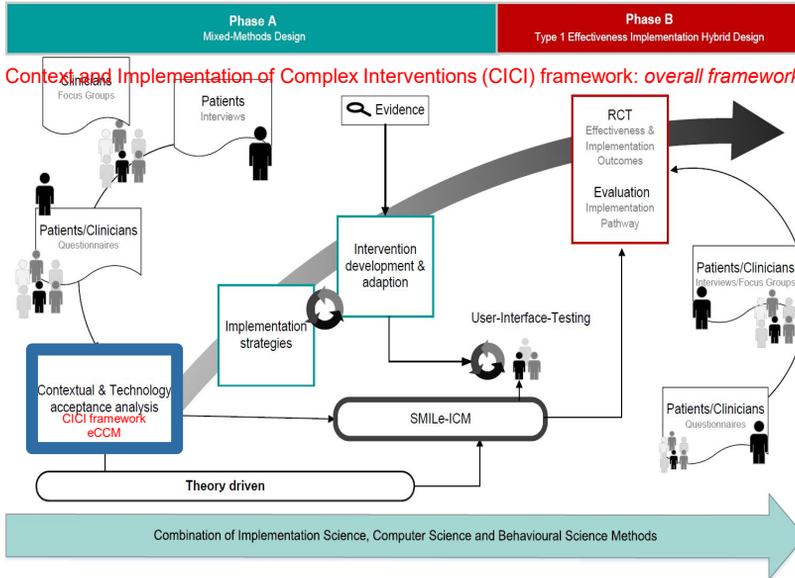
SMILe Project – overview

USE OF THEORY

Phase A
Mixed-Methods Design

Phase B
Type 1 Effectiveness Implementation Hybrid Design

Context and Implementation of Complex Interventions (CICI) framework: *overall framework*

Clinicians Focus Groups

Patients Interviews

Evidence

Patients/Clinicians Questionnaires

Intervention development & adaption
Beh. Change wheel

Implementation strategies

Contextual & Technology acceptance analysis
CICI framework eCCM

User-Interface-Testing

SMILe-ICM

Theory driven

RCT
Effectiveness & Implementation Outcomes

Evaluation
Implementation Pathway

Patients/Clinicians
Interviews/Focus Groups

Patients/Clinicians
Questionnaires

Combination of Implementation Science, Computer Science and Behavioural Science Methods

SMILe intervention: The Thing

SMILe-ICM: Integrated eHealth facilitated care model for alloSCT

eCCM [A]
Self-Management Support - Delivery System Design - Clinical Decision Support - Clinical Information System - eHealth education

Four Intervention Modules [B]
(1) Monitoring & Follow-up of vital signs, symptoms & health behaviour
(2) Infection Prevention
(3) Physical Activity
(4) Medication Adherence

alloSCT Patient

NEW SMILeTechnology [C1]
(technology delivery)

SMILeAPP & SMILeCare

alloSCT Centre
Multidisciplinary transplant team

NEW CC/APN [C2]
(human delivery)

Management acute deterioration of health (care algorithms)

Self-management & decision support (care protocols)

Enters vital signs, symptoms, health behaviour

Self-management information, visualization

Transferred to alloSCT team and CC/APN

12 Face-to-face visits provided by CC/APN as part of follow-up care

The Basel Heptagon of Implementation Science

- Key elements of implementation science to successfully cross from the trial world to real world settings

SMILe Project – overview

# Mixed -Methods Approach in Context Analysis

- Stakeholders' views on practice patterns, unmet needs, practice patterns & use of technology
  - Some findings:
    - Current clinical practice is mostly acute care driven, limited interdisciplinarity
    - Weak chronic illness management e.g. self-management support
    - Health behaviors issues: medication adherence, physical activity and infection prevention.
    - Issues in hospital-to-home transitions.
    - Patients' insecurity about recognizing, judging and acting upon symptoms.
    - Openess for eHealth yet not supplanting human contact.
    - Health economic data essential for reimbursement

Leppla et al. European Journal of Oncology Nursing 2020 Apr;45:101723.

Clinical settings (Phase A)
University Hospital Freiburg (Germany)
University Hospitals Basel & Zürich (Switzerland)

The Basel Heptagon of Implementation Science

- Key elements of implementation science to successfully cross from the trial world to real world settings

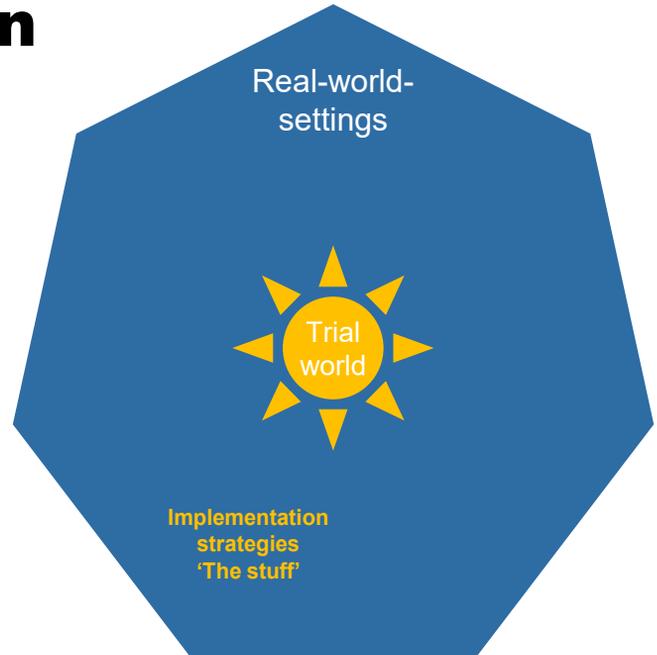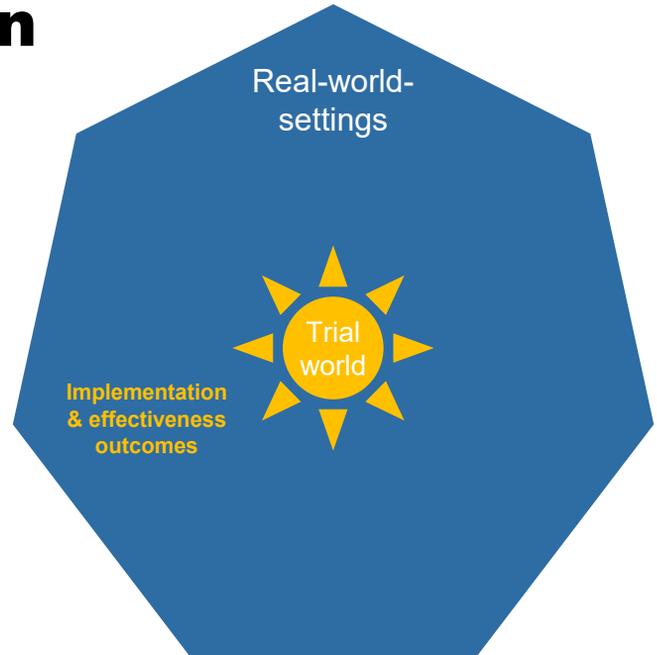# SMILe Project – overview
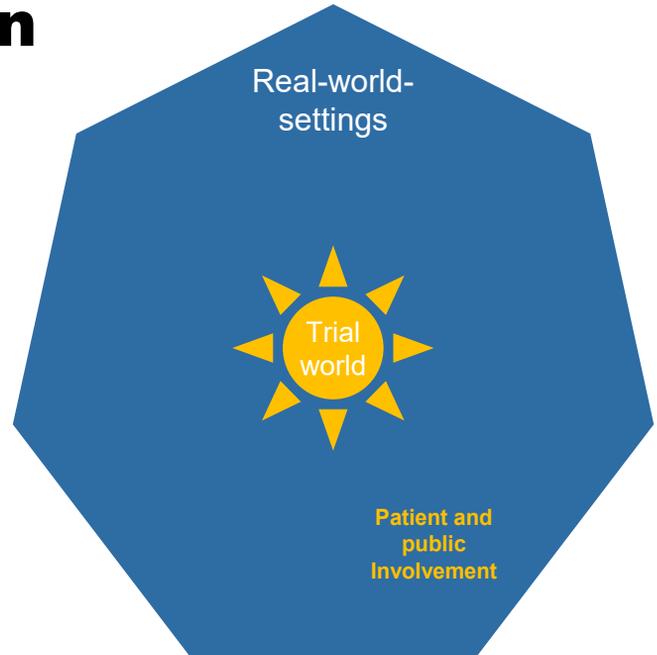
Patient and Public involvement in SMILe

- Stakeholders' views on practice patterns, unmet needs, practice patterns & use of technology
- Health insurers already asked for evidence base needed for sustainability (i.e. reimbursement)
- Co-creation SMILe integrated care model (e.g. user-centered design)
- Determining implementation strategies
- Evaluation

National Institute for Health Research. INVOLVE. Briefing notes for researchers: involving the public in NHS, public health and social care research. Eastleigh. 2012

Patient organizations

Clinicians

Health Insurance

Patients & Caregivers

The Basel Heptagon of Implementation Science

- Key elements of implementation science to successfully cross from the trial world to real world settings

Real-world-settings

Trial world

Implementation strategies 'The stuff'

SMILe Project – overview
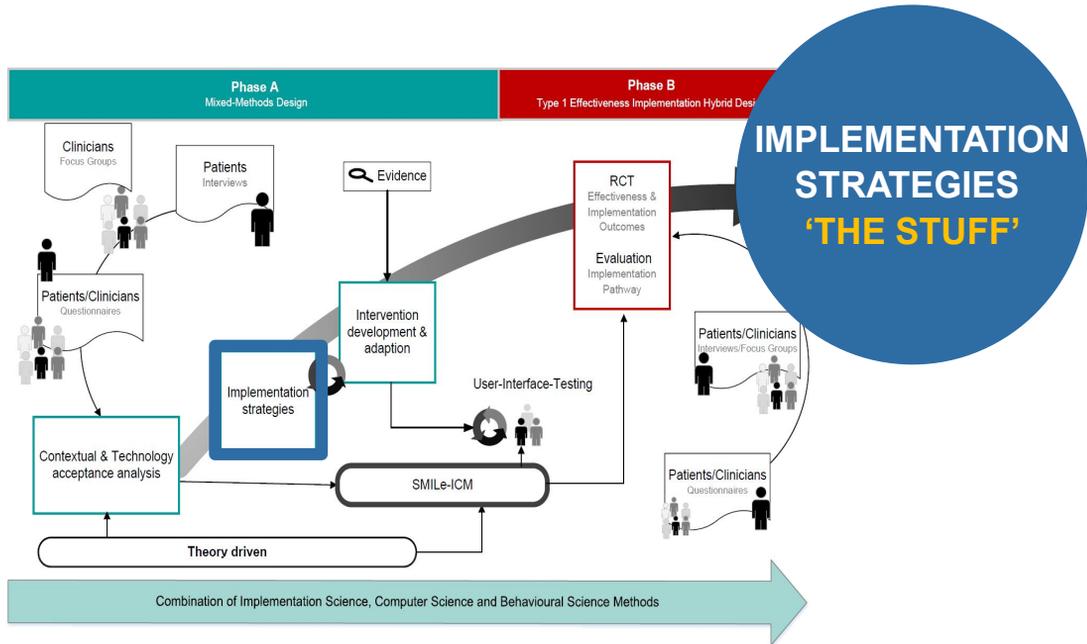
Implementation strategies for SMILe: the Stuff

Before SMILe Project Started	Pre-Work (Phase A)	Testing and Implementation (Phase B)	Sustainement
Access new funding	⟶		
Develop academic/clinical partnership	⟶		
Inform local opinion leaders	⟶		
	Conduct local needs assessment and consensus discussion	⟶	
	Obtain and use patients and family feedback	⟶	
	Organize clinician implementation team meetings	⟶	
	Develop educational material ➔ CC protocol		
	Revise professional roles ➔ Identify champions: CC/APNs ➔ Train/prepare CCs/APNs		
	Visit other sites ➔ FIB settings		
		Use mass media to spread clinical innovation	⟶
		Provide clinical supervision	⟶

Defined implementation strategies for the USB based on Powell et al. (2015) [120]

The Basel Heptagon of Implementation Science

- Key elements of implementation science to successfully cross from the trial world to real world settings

Real-world-settings

Trial world

Implementation & effectiveness outcomes

Dual aims of SMILe:
## *effectiveness & implementation*

3. **To evaluate** *effectiveness outcomes* **of the SMILe-ICM** in view of re-hospitalization rate, (primary outcome), total healthcare utilization costs, medication non-adherence, treatment burden, health-related quality of life (HRQL), quality-adjusted life year (QALY), acute and chronic GvHD incidence and grade and overall survival rate (secondary outcomes) in the first year post-alloSCT.

4. **To evaluate** *the implementation* **of the SMILe-ICM** regarding feasibility, acceptability, appropriateness, and fidelity (implementation outcomes) and **to evaluate the implementation pathway** from patients and health care professionals perspective.
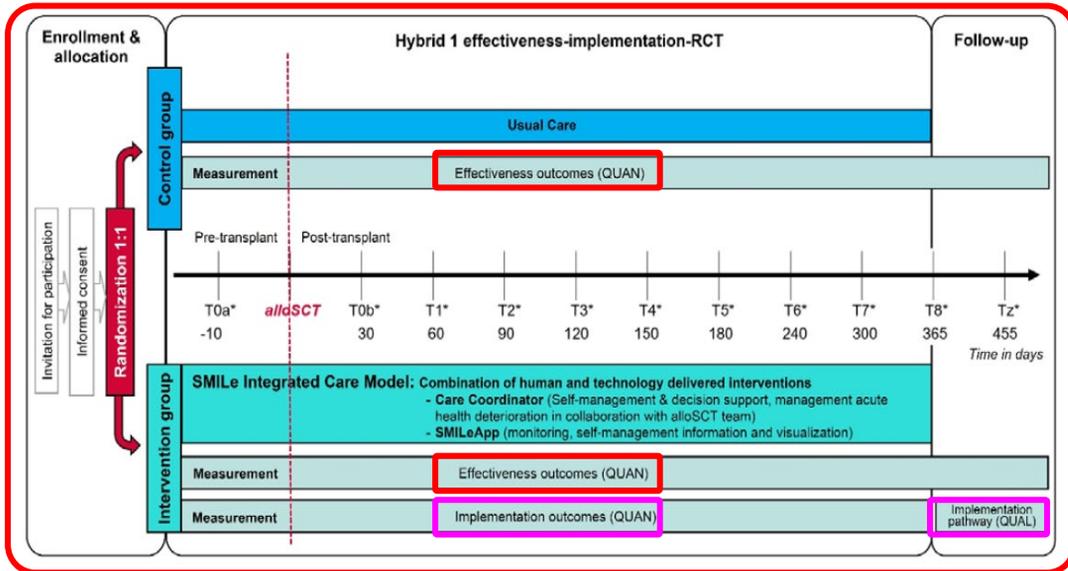
The Basel Heptagon of Implementation Science

▪ Key elements of implementation science to successfully cross from the trial world to real world settings
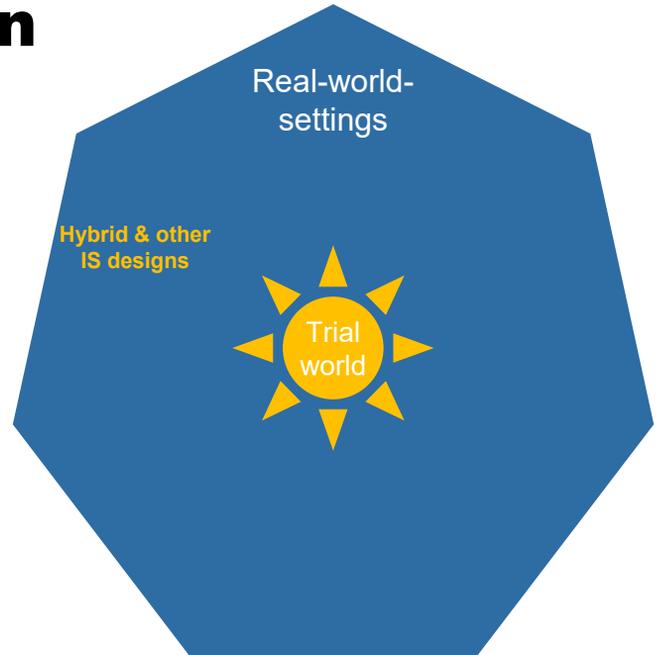
SMILe Project – overview
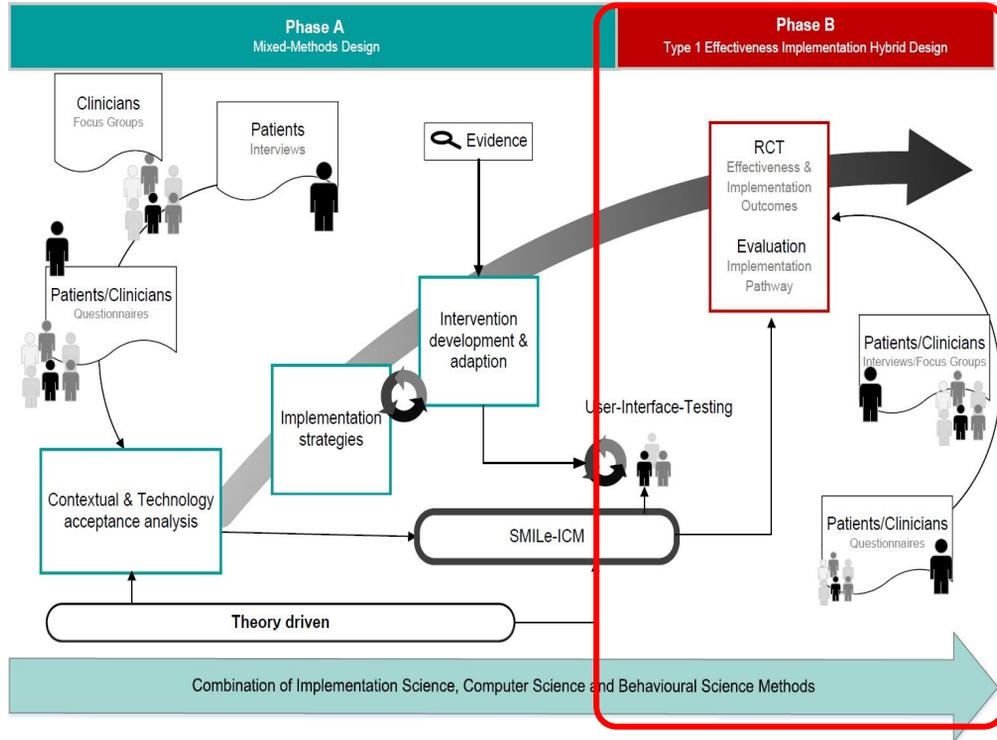
SMILe Project – Hybrid 1 design

SMILe Project – Pilot results FiB

- Excellent acceptability and appropriateness of SMILe-ICM (patients and clinicians).

- SMILe-ICM operationally feasible in clinical settings: technology & human component integrated in care processes of allo-SCT center.

- Ehealth component operational – only small adaptations needed – no major issues occurred at patient nor hospital side.

- SMILe–ICM implementation science study design is feasible.

- No issues with patient recruitment (except during the COVID-19 lockdown period).

- No issues with patient retention in study.

- First effectiveness outcomes available 2021.

Conclusions
Implementation science:

1. Reduces research waste 2: it is the methodological approach to translate research evidence in clinical practice

2. Applies a variety of methods and strategies to successfully cross from the trial to real world settings beyond the traditional experimental clinical research designs

3. Implementation science can strengthen the research pipeline for powerful real-world translation

4. Conducting implementation science requires an adapted and supporting research infrastructure to achieve IMPACT.

Implementation science:
Making research findings more powerful for use in clinical practice

sabina.degeest@unibas.ch