

Social-Behavioral Science Core (SBSC) in IMPAACT

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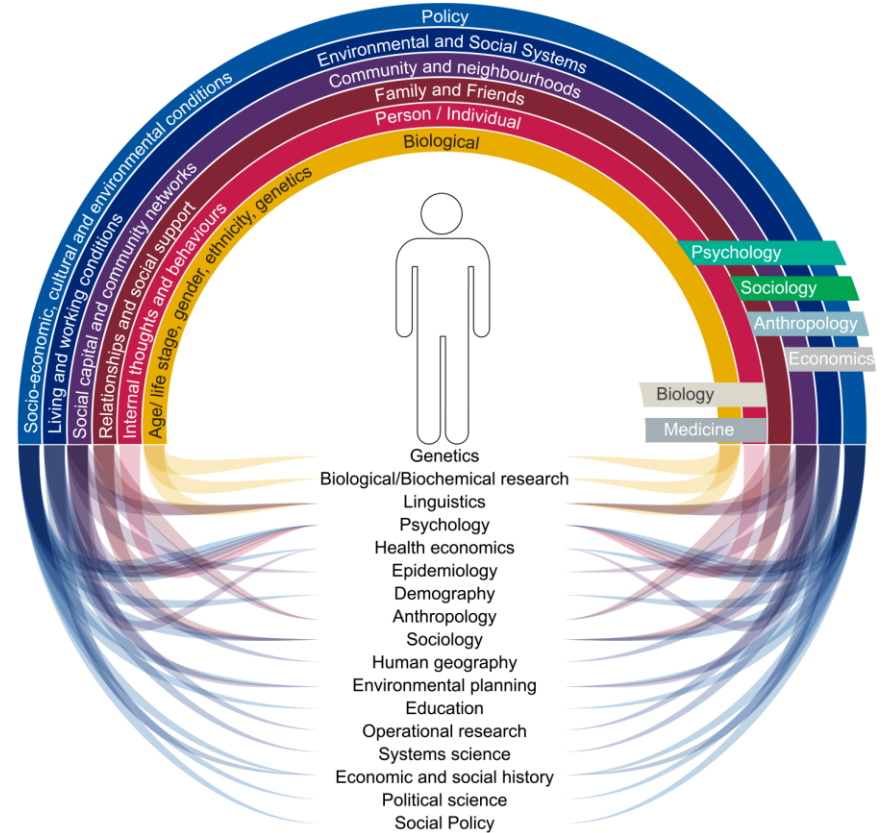
ANNUAL MEETING
2022

Social Behavioral Sciences

What is Behavioral and Social Sciences Research? (National Institutes of Health)

“Behavioral” ...refers to what people do, as well as what drives them to do things, and it involves psychological processes like emotion.

“Social” ...reflects how individuals interact with each other: in small groups, families, and communities, as well as within populations and in society.



*Conceptualising the contributions of
behavioural and social science disciplines
Behavioural Science and Public Health
Network*

Social Behavioral Sciences

Social Behavioral factors WILL influence outcomes of biomedical trials with human participants. Measuring and working WITH social behavioral factors decreases unknowns.

What is the role of SBS in HIV Networks?

In addition to supporting protocols, procedures and implementation approaches that align with best practice... the benefits of integrating of SBS RESEARCH into biomedical trials have been recognized for decades

SBS offers insights into the factors (thoughts, feelings, beliefs, motivations, relationships, experiences) underlying the human behaviors that influence clinical trial outcomes

"You know, maybe we under-invested in research on human behavior," Collins said. "I never imagined a year ago, when those vaccines were just proving to be fantastically safe and effective, that we would still have 60 million people who had not taken advantage of them because of misinformation and disinformation that somehow dominated all of the ways in which people were getting their answers." – Francis Collins News Hour

Social Behavioral Sciences Research

Behavioral Social Sciences Research (BSSR)

Basic BSSR:

Understanding priority populations and risk settings

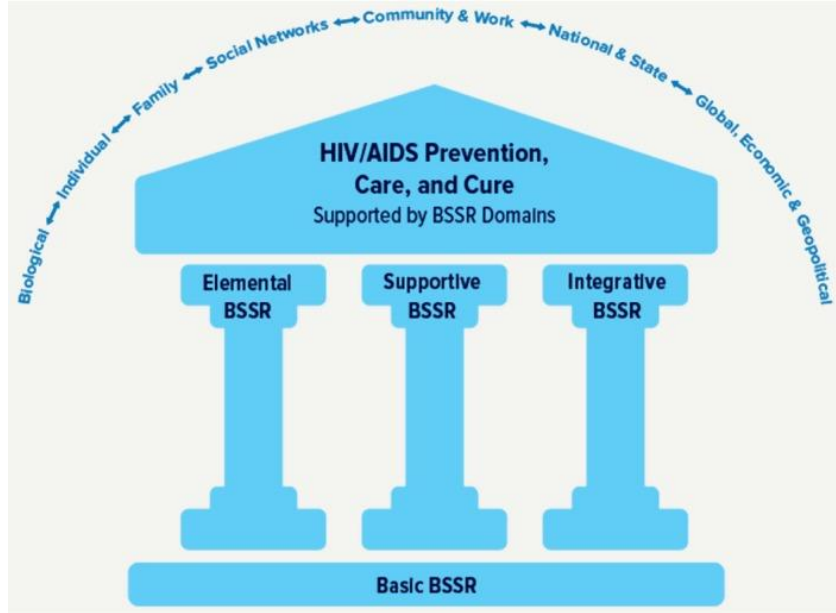
Elemental BSSR:

IMPAACT 2016 – Elemental Study- Evaluating a Group-Based Intervention to Improve MH and ART adherence

development and trials

Integrative BSSR:

Contributing to the effective implementation of combination and multilevel strategies

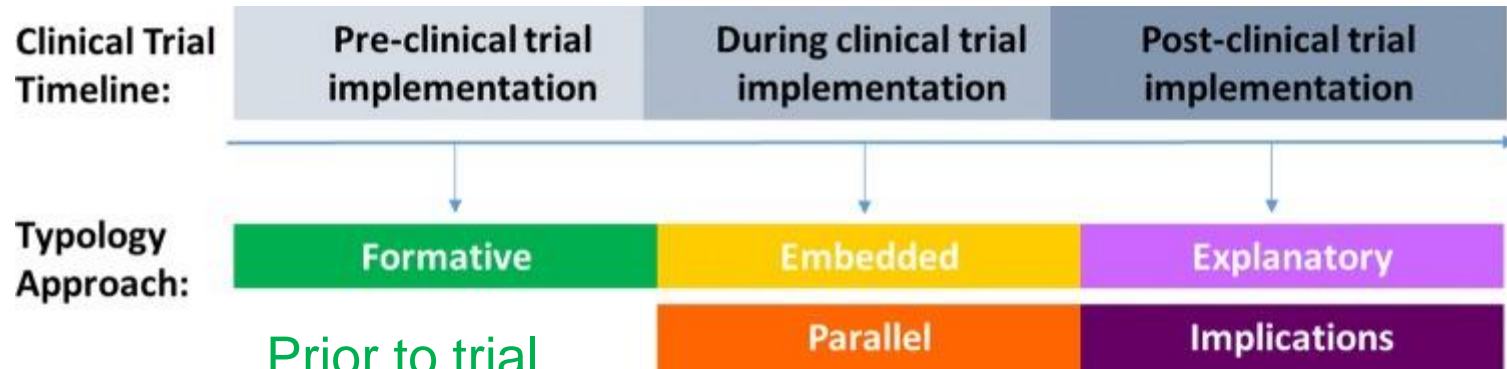


Basic BSSR	Understanding priority populations and risk settings
Elemental BSSR	Improving behavioral and social interventions
Supportive BSSR	Strengthening biomedical HIV product development and trials
Integrative BSSR	Contributing to effective implementation of combination and multilevel strategies

Dube, Auerbach. Stirratt, Gaist 2019

(Gaist and Stirratt, 2017, JAIDS, updated)

Typology of SBS in Clinical Research (Corneli et al *AIDS and Beh* 2019)



Prior to trial

Optimize fit in and responsiveness to community

Optimize aspects of study and procedures

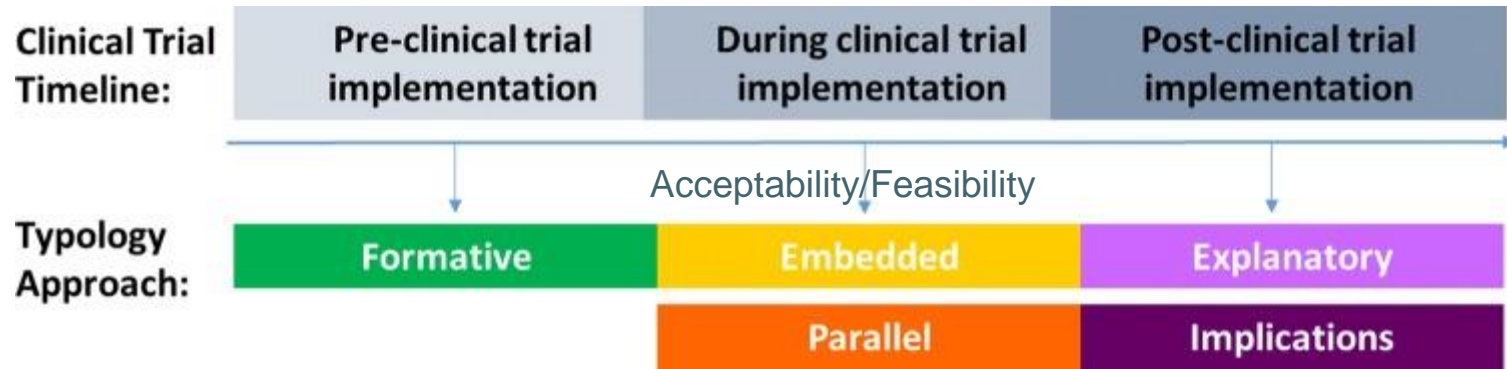
2003b/A5300b – Formative, Embedded Adherence

How should the study be presented to community?

How could the study support adherence?

What will participants think about procedures?

Typology of SBS in Clinical Research (Corneli et al *AIDS and Beh* 2019)



Collection and use of social behavioral data

- Closely integrated within the study objectives and outcomes (embedded)
- To investigate a separate but related SB hypothesis (parallel)

Does risk perception influence outcome?

Do experiences on study influence uptake?

Are outcomes moderated by social/structural factors?

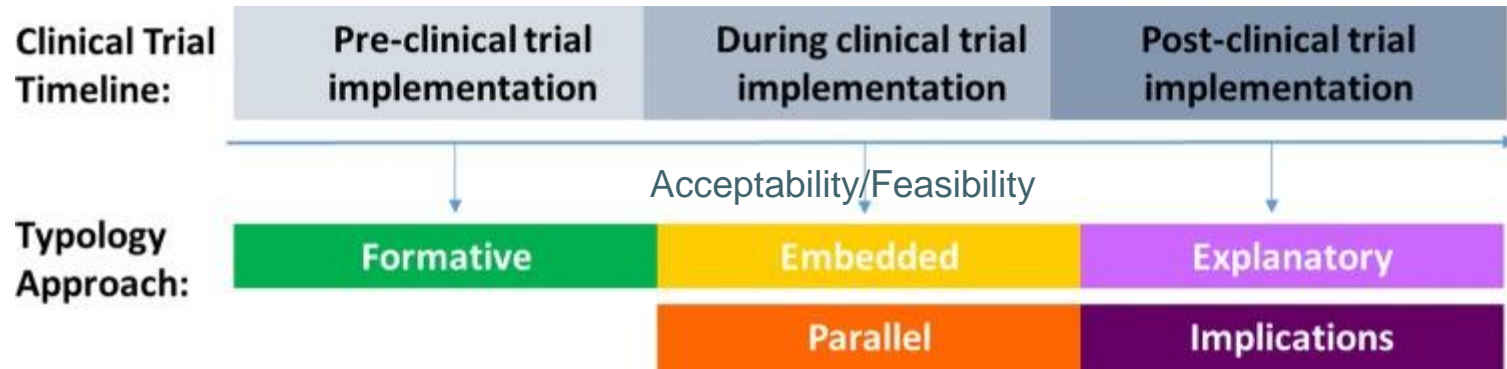
What is the treatment decision making process?

Prevalence and impact of IPV or ACE?

Validity of methods/measures?

Several IMPAACT Studies include Acceptability and Feasibility
2020, 2024, 2035

Typology of SBS in Clinical Research (Corneli et al *AIDS and Beh* 2019)



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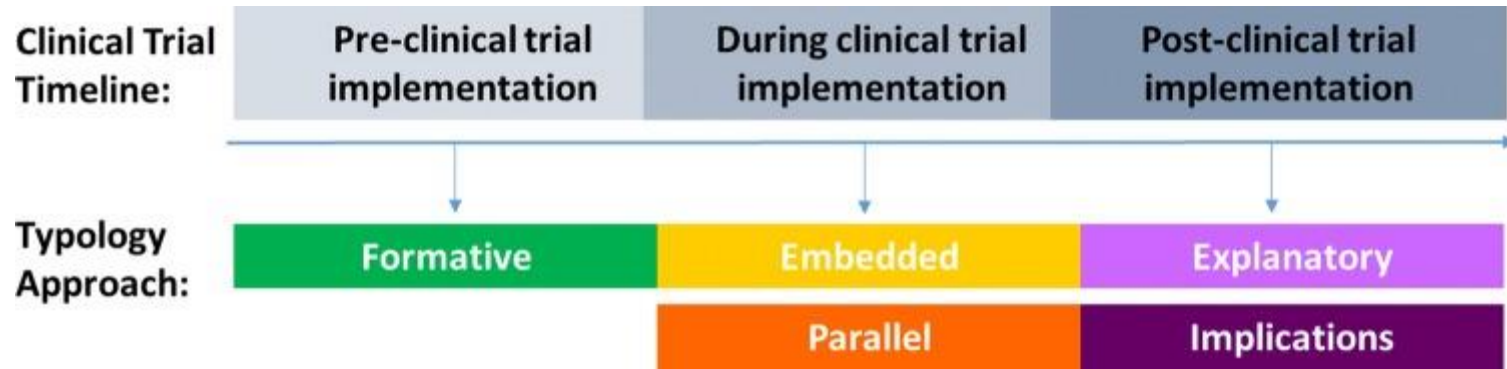
2017 – Embedded Mixed Methods Acceptability and Feasibility

2036 – Embedded Mixed Methods Acceptability and Feasibility

2009 – Embedded Adherence and Social Determinants and Mixed Methods

2010 – Embedded Multiple Measures of Adherence and Correlates Quantitative

Typology of SBS in Clinical Research (Corneli et al *AIDS and Beh* 2019)



Planned, added as amendment, or independent work

- Investigation/exploration of SB factors after the conclusion of the trial/collection of final outcomes

Do social harms persist after trial end?

Do people have delayed benefits from participating in an influential study?

Is product uptake different for those who participated in product efficacy trials?

Observations and Recommendations

- Review of studies enrolling and in development over the past 5 years within the IMPAACT Network

Progress and Strengths

- consistently include measures of product adherence, and treatment acceptability/feasibility
- are beginning to use more sophisticated approaches to understanding experiences with specific treatments
- increasing interest in patient centered outcomes
- greater recognition of implementation science
- increasing expertise in SBS

Areas for Growth

- promote standardized formative work
- harmonize SB measures
- Identify a bank of patient centered outcomes measures for use in all protocols
 - beliefs, attitudes, preferences, context

SBS Core

Social Behavioral Science Core



AWG

Established the
Adherence Working Group

Open group

Monthly discussions
focused on measurement
and support of adherence

SBSC

Standing committee mix of
within and outside of
IMPAACT network
Experts in SBS

Monthly and ad hoc

Review Concepts,
Proposals and Protocols

Advise on measures

V2.0

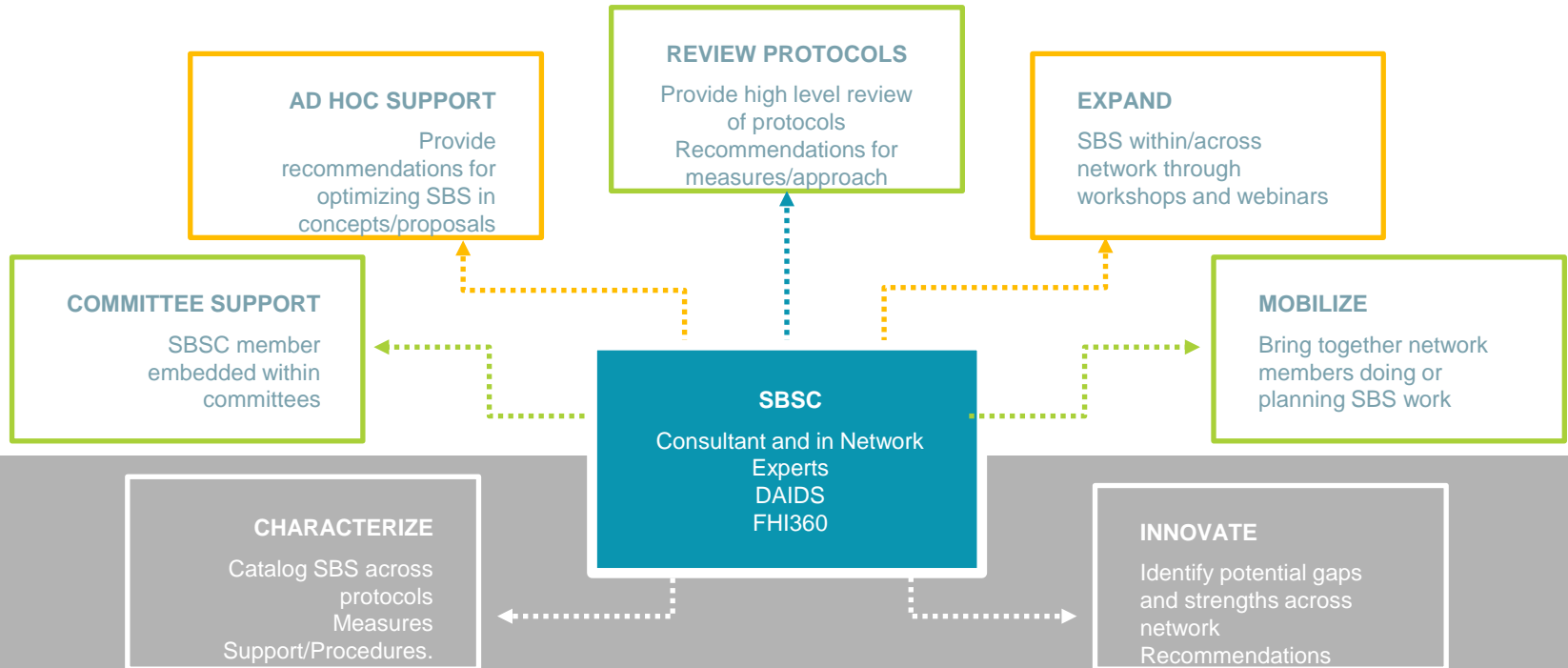
Nested core members within
scientific committees

Collaboration in the development
of studies

Review of concepts in concert with
other groups in the
multidisciplinary protocol review
group (MPRG)

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Operations Within the IMPAACT NETWORK



SBSC

Operations Within the IMPAACT NETWORK

Tuberculosis: Jessica Haberer and Nicole Montañez

Complications and Comorbidities: Kenneth Ngunjiri and Jennifer Libous

Treatment: Rivet Amico

Cure: Rachel Kidman

COMMITTEE SUPPORT

SBSC member
embedded within
committees

SBSC

Consultant and in Network
Experts
DAIDS
FHI360



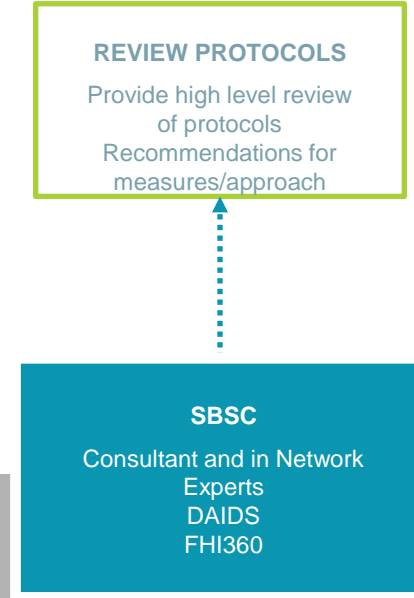
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- Recommendations for measures of SBS factors
- Best practices for adherence measurement and support?
- **Contact:** Nicole Montañez, Jennifer Libous, Rivet Amico

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- As part of multidisciplinary protocol review group (MPRG) investigators receive comments from the SBSC
- Two independent reviewers using standardized form
- Full core team discussion
- Consolidated feedback and recommendations provided



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Webinars, panel discussions and workshops are planned for quarter 3 to expand network-wide SBS knowledge and SBSR skills

EXPAND

SBS within/across network through workshops and webinars

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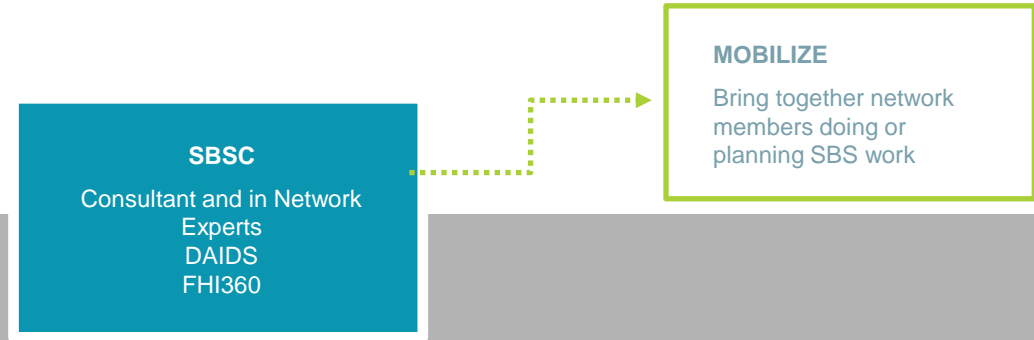
Consultant and in Network
Experts
DAIDS
FHI360

Sites have been queried on:

- **Interest and expertise in SBS**
- **Topics of highest relevance**

SBSC

- **SBS expertise is present in CRSs, scientific committees, and protocol teams**
- **We are working to identify and invite senior and emerging SB scientists to share experiences (webinars, panel discussions, topic specific meetings)**



- **Mapping areas of SBS expertise within IMPAACT can facilitate ongoing and innovative work**

SBSC

CHARACTERIZE AND INNOVATE

Our ongoing work cataloging SBS in IMPAACT studies identified SB factors measured with some consistency (adherence, acceptability, context [food security, housing stability])

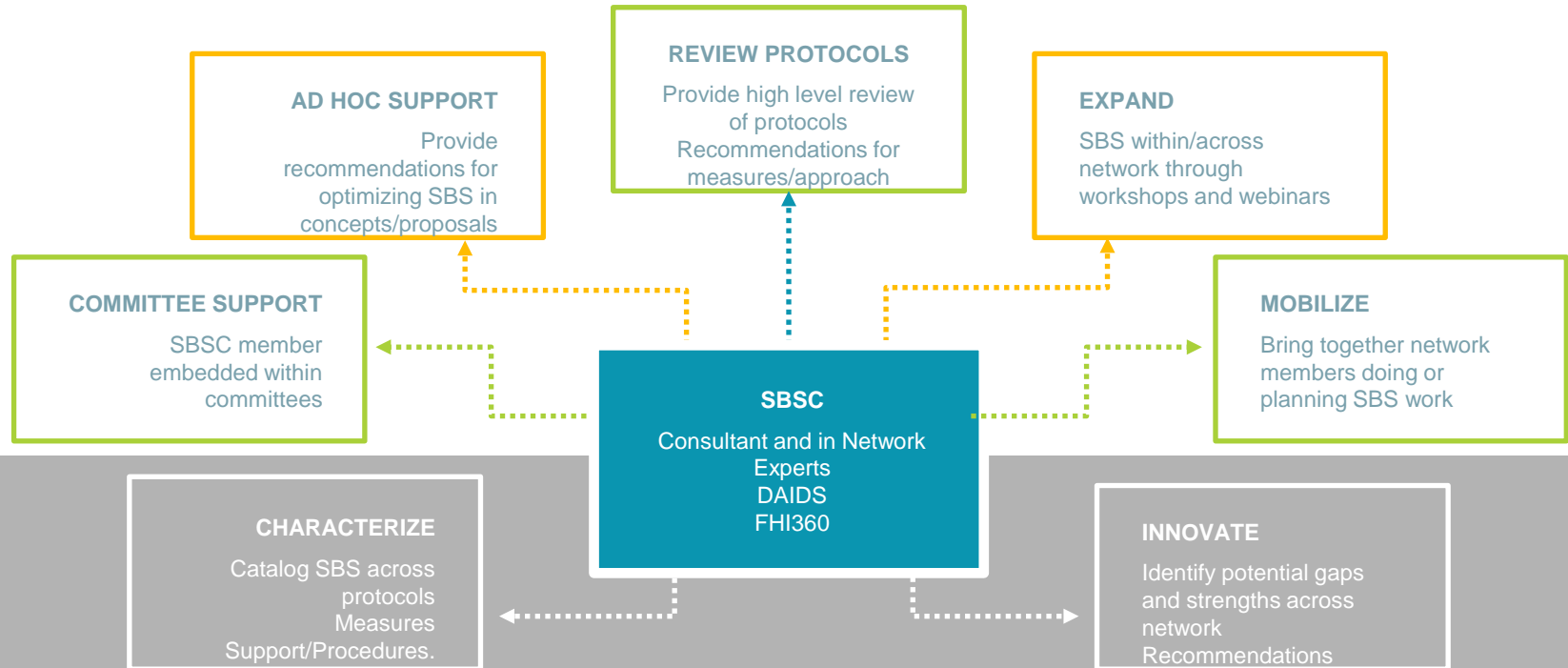
INNOVATIONS

- Harmonize certain SB and context measures → Cross protocol/study evaluations
- Study clinical trial implementation
- Use collected data from studies to evaluate the validity of measures to build evidence informed measurement strategies



SBSC

As we enter a new structure, we look forward to continued growth of SBS in the IMPAACT NETWORK



Acknowledgments

*SBSC members: Rivet Amico, Jessica Haberer, Rachel Kidman, Kenneth Ngure,
Jennifer Libous, Nicole Montañez, Ellen Townley, Tafadzwa Kasambira*
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THANK YOU!

We appreciate the ongoing support of the Network, protocol teams, scientific committees, and clinical research site team members. We look forward to a productive year together.