

Support **U**tilisation of **S**ustainable and **T**ailored **I**nnovative methods for HTA

AN EU-WIDE INITIATIVE TO BUILD **A SUPPORTING
INFRASTRUCTURE** TO ENSURE ONGOING IMPLEMENTATION
OF THE LATEST AND FIT-FOR-PURPOSE HTA
METHODOLOGIES AND TOOLS IN PRACTICE

Coordination and Support Action (2024-2027)

Overview and first results
Wim Goettsch, Coordinator



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The SUSTAIN-HTA project is funded by the European Union's Horizon Europe programme under the grant agreement No 101136318. The UK participant is supported by UKRI grant No 10106859 (National Institute for Health and Care Excellence). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union, the United Kingdom, HaDEA or UKRI. Neither the European Union, the United Kingdom, nor the granting authorities can be held responsible for them.

Some initial considerations

- Many investments in HTA methodologies through EU projects for more than ten years
- Developments in how HTA bodies work; from systematic reviews and large indications to submission-based work for small and targeted populations.
- However, developments in HTA methodologies currently may often not match to the needs of HTA bodies
- Can we better align HTA needs to academic HTA methods development?
- Can we learn from some national interactions between HTA bodies and academics?



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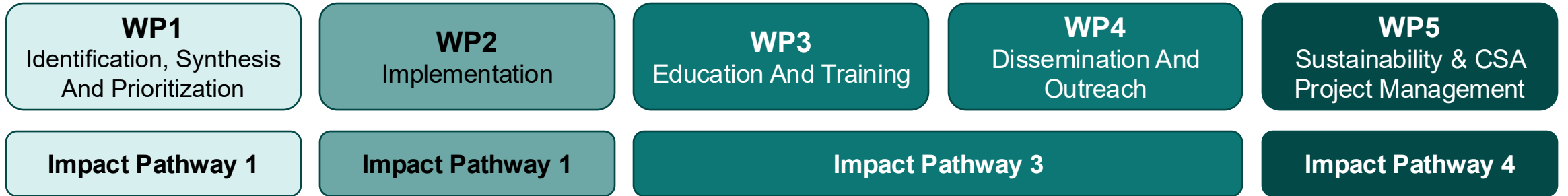
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HORIZON-HLTH-2023-IND-06-01 - Supporting the uptake of innovative Health Technology Assessment (HTA) methodology and advancing HTA expertise (call text)

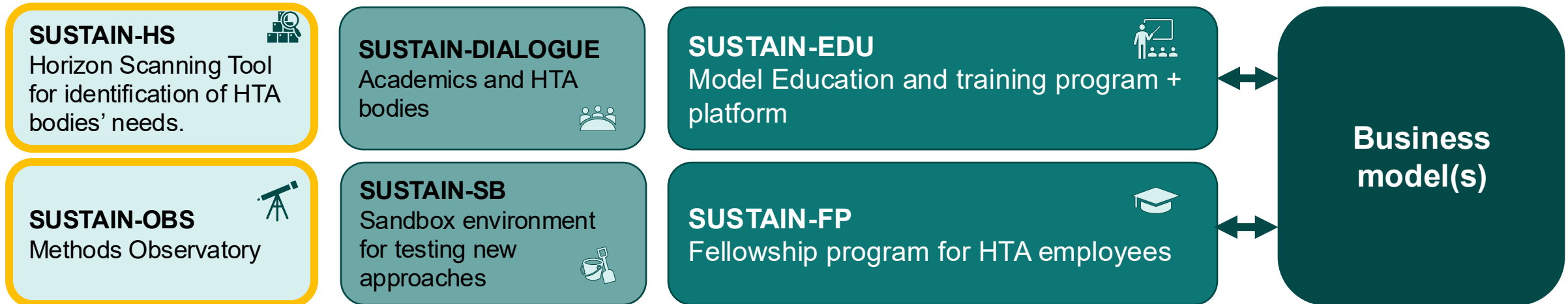
- Identify innovative methods and tools, in particular those developed by EU-funded projects able to address HTA bodies' needs
- Identifications of barriers to the uptake of the methods (and potential associated tools, e.g. open-source software to run cost-effectiveness analyses)
- Use cases (based on needs identified by HTA bodies) to facilitate the endorsement of innovative methods
- Development of an implementation plan including supporting tools and training modules
- Recommendations for broader dissemination

Identify the methodological needs of HTA bodies at EU and national level!

Building blocks and outcomes of the project

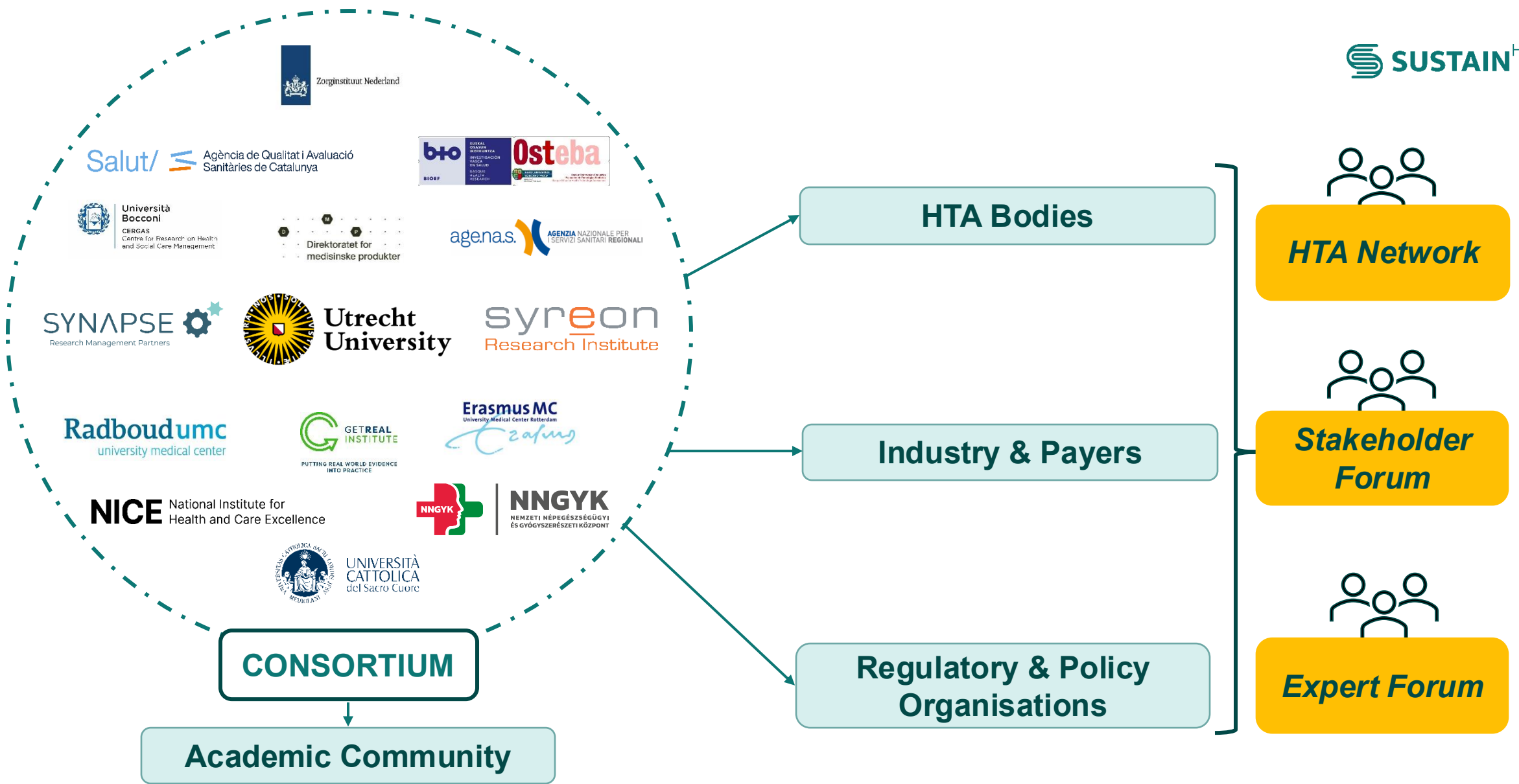


OUTCOMES



Consortium composition SUSTAIN-HTA

Partner #	Partner Name	Short Name	Partner Type	Country
1 - Coordinator	Utrecht University; The Division of Pharmacoepidemiology and Clinical Pharmacology	UU(-PECP)	 University	NL
2	Bocconi University; Centre for Research on Health and social care management	UB(-CERGAS)	 University	IT
3	National Institute for Health & Care Excellence	NICE	 HTA Body	UK
4	Erasmus Universitair Medisch Centrum Rotterdam	EMC	 University	NL
5	Zorginstituut Nederland	ZIN	 HTA Body	NL
6	Stichting Radboud Universitair Medisch Centrum	RUMC	 University	NL
7	Syreon Kutato Intezet Korlatolt Felelossegu Tarsasag	SRI	 SME	HU
8	Fundacion Vasca de Innovacion e Investigacion Sanitarias	OSTEBA	 HTA Body	ES
9	GetReal Institute	GETREAL	 NGO	NL
10	Synapse Research Management Partners S.L.	SYNAPSE	 SME	ES
11	Nemzeti Népegészségügyi és Gyógyszerészeti Központ	NCPHP	 HTA Body	HU
12	Agenzia Nazionale per i Servizi Sanitari Regionali	AGENAS	 HTA Body	IT
13 (Affiliated)	Universita Cattolica del Sacro Cuore (Affiliated entity of 12. AGENAS)	UCSC	 University	IT
14	Agencia de Qualitat i Avaluacio Sanitaries de Catalunya	AQUAS	 HTA Body	ES
15	Direktoratet for medisinske produkter	NOMA	 HTA Body	NO



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1. SUSTAIN-HS Tool to continuously identify HTA Body Needs for New Methods

This section presents methodological needs of European HTA bodies, as identified by the SUSTAIN-HTA project. You can use the search box on the right to narrow down the list to needs that include your search term in the title, bullet-point summary, or full description shown under 'Read More'.

(1) Real-World Evidence (RWE)

- Demonstration projects to facilitate the adoption of advanced scientific methods
- Collaboration and dialogue between academia and HTA bodies
- Application of machine learning (ML) and generative AI to support causal inference

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(2) Indirect Comparisons

- Addressing heterogeneity across studies' populations
- Accommodating complex evidence networks
- Incorporating RWE evidence in indirect comparisons

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(3) Validation of Surrogate Endpoints

- Fit-for-purpose validation of surrogate endpoints

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ASCERTAIN

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AI/ML for Treatment Effect Prediction

Category: Predictive Modelling; ML/AI; RWE

Using ML/AI to predict treatment effects of orphan diseases (small datasets).

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Algorithm for estimating the fiscal impact of new health technologies

Category: Costing & Resource Use; Societal Value

A framework for the estimation of the fiscal impact deriving from the health gains of new technologies (e.g., productivity gains, consumption increase)

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Analytical framework for determinants of HTA recommendations

Category: Appraisal

An analytical framework for explaining the determinants of HTA coverage recommendations, linking evidence quality, social value judgements, and other

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Baseline Risk Score in cost-effectiveness modelling

Category: RWE; Heterogeneity

A cost-effectiveness model that integrates individual patient-level data and predicts personalised costs and effects.

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Checklist for assessing OBMEA feasibility in rare diseases

Category: Pricing/Payer

Criteria for use by a Health Technology Assessment (HTA) body or Marketing Authorisation Holder (MAH) to determine whether an Outcomes-Based Managed E

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GREG

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CHEERS-AI

Category: Reporting Standards & Best Practice

A Consolidated Health Economic Evaluation Reporting Standards for Interventions that use AI.

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ClinFlow

Category: Data Mining; ML/AI; Data Exploration & Visualization

An interactive visual interface that allows the domain expert to process and perform advanced exploratory tasks on clinical trial datasets, without th

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CohortMethod R package

Category: RWE; Predictive Modelling

An R package for conducting new-user cohort studies using observational databases structured according to the Observational Medical Outcomes Partnersh

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Core outcome set for diabetes

Category: PROs; PROMs

A person-centred core outcome set (COS) for diabetes that includes patient-reported outcomes (PROs) and clinical outcomes, with emphasis on psychosoci

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Core outcome set for inflammatory bowel disease (IBD)

Category: PROs; PROMs

A core outcome set (COS) for inflammatory bowel disease (IBD) that includes patient-reported outcomes, biomarkers, and case-mix variables, with recomm

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Core outcome set for lung cancer

Category: PROs; PROMs

A patient-centred core outcome set (COS) for lung cancer that includes both clinical and patient-reported outcomes.

Core outcome set for metastatic breast cancer (MBC)

Category: PROs; PROMs

A core outcome set (COS) for metastatic breast cancer (MBC) that covers baseline

Core outcome set for multiple myeloma

Category: PROs; PROMs

A European consensus-based, standardised core outcome set (COS) for patients with

Cross-NMA/NMR

Category: Evidence Synthesis; Indirect Comparisons; RWE

A suite of Bayesian Network Meta-Analysis (NMA) and Network Meta-Regression (NMR)

crossnma R Package

Category: Evidence Synthesis; RWE

An R package crossnma to perform cross-format (IPD and AD) and cross-design (RCT and NRS) NMA and network

A living observatory of HTA methods



Identify EU-developing and tools (YIMI & H2020)

Scan scientific international ISPOR, ISP

Conduct systematic review to identify additional developers

Link structural coordination subgroups

Relation to other existing and new EU HTA initiatives

EU HTAR CG and its subgroups, for instance, on Methodology

- SUSTAIN-HTA will focus on providing knowledge that SG may use on Methodology for updating their guidelines

HAG insight project to build capacity/knowledge for the implementation of the EU HTAR

- SUSTAIN-HTA education and training program will focus on new, innovative HTA methods, which could be supplementary to the education/training planned in the tender, that is mainly focused on existing methodology

Technical Support Instrument (TSI) on HTA

- SUSTAIN-HTA might provide additional options through its planned fellowship program for less experienced HTA bodies to gain further expertise.

Boosting competitiveness and innovation through SUSTAIN HTA!

- Establishing a structured actualised HTA bodies that will timely implement methods.
 - First overview demonstration of sustainability
- Providing a fair and HTA methods developed by academic and private organisations.
- Creating HTA bodies can join, with the stakeholders, to support development of innovative HTA methodology.

ENSURE STRUCTURAL AND SUPPORT SUSTAINABLE STRUCTURES THAT CONTINUE THE EXISTING AND NEW EU RESEARCH EFFORTS OF THESE PROJECTS AND ENFORCE IMPLEMENTATION AND RESOURCE BUILDING IN HTA PRACTICE PROJECTS INTERACTION BETWEEN



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Thank you for your attention



<https://sustain-hta.org/>



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