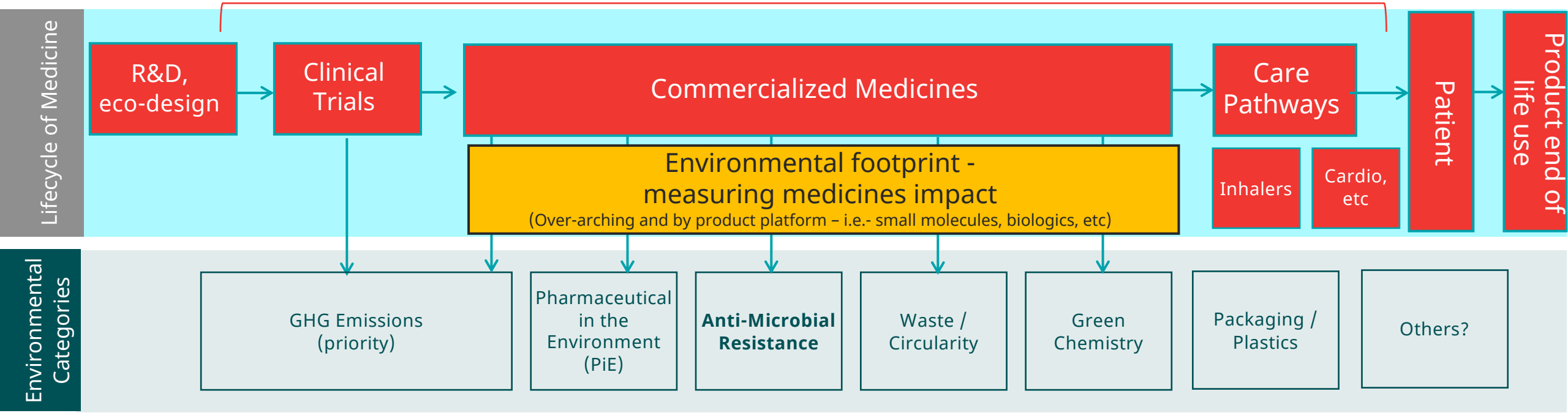
Medicines Environment Standardization Programme

Healthcare ecosystem – medicines environment standardization programme

BSI convening a multi-stakeholder, consensus-driven standards programme for defining and aligning terminology, methodologies, and measurement of environmental impact of medicines.



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Anti-Microbial Resistance

What is Antimicrobial Resistance?

AMR is a top 10 global public health threat according to the WHO and is expected to get worse.
It threatens to undermine the basis of modern medicine by rendering the antibiotics used to treat and prevent infections ineffective, making medical advances. In 2019, antimicrobial resistant bacteria accounted for 1.27m deaths and contributed to another nearly 5m deaths during the same year, according to IHME/The Lancet.

BSI Approach - Project

Industry Standard - following extended relationship building, the AMR Alliance engaged BSI facilitate development of a private standard by working with the Alliance and multiple industry stakeholders.

Certification Scheme- The Alliance and BSI will develop a certification scheme and serve a governance and program management role that will enable antibiotic manufacturers to demonstrate that the requirements of the Standard have been satisfied.

Benchmark / Data - Pharmaceutical environmental expertise from the consulting business has served as a critical role for the development of the standard and in supporting certification assessment model for the future scheme.

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bsi Minimized risk of Antimicrobial Resistance KITEMARK™

Kitemark 13252
AMRIA: Antibiotic Manufacturing Standard

Nordics (5 countries) - Antibiotic tenders – certification award criteria

Nr	Requirement	Information to provider
1	The product offered should be manufactured by a supplier that can demonstrate compliance to AMRIA Antibiotic Manufacturing Standard or similar manufacturing standard that combats antimicrobial resistance throughout the supply chain. To achieve the highest score, this must be certified by a third party or certification process has started.	Enter answer option. The purpose of the requirement is to achieve the least possible environmental impact in the manufacturing processes for the products and to avoid antibiotic resistance as a result of the production of the offered product. The supplier should provide evidence upon request of compliance to the standard. https://www.amrindustryalliance.org/shared-goals/common-antibiotic-manufacturing-framework/

	Answer option	Score	Justification
1	The supplier is compliant to AMRIA Antibiotic Manufacturing Standard or similar standard that combats antibiotic resistance throughout the whole supply chain, and this is certified by a 3. Party. (Specify which standard and 3rd party certification has been used, or will be used)	10	The supplier fulfills the requirement.
2	The supplier is compliant to AMRIA Antibiotic Manufacturing Standard or similar that combats antibiotic resistance throughout the whole supply chain, but this is not certified by a 3. Party.	8	The supplier fulfills the requirement to a large extent.
3	The supplier is compliant to AMRIA Antibiotic Manufacturing standard in parts of the supply chain (specify which part).	5	The supplier partially fulfills the requirement.
4	Does not follow the AMRIA Antibiotic Manufacturing standard.	0	The supplier does not fulfill the requirement.
5	Don't know.	0	The supplier does not fulfill the requirement.
6		0	The supplier does not fulfill the requirement.

Ecosystem-wide approach to consensus – BSI convening community of practice

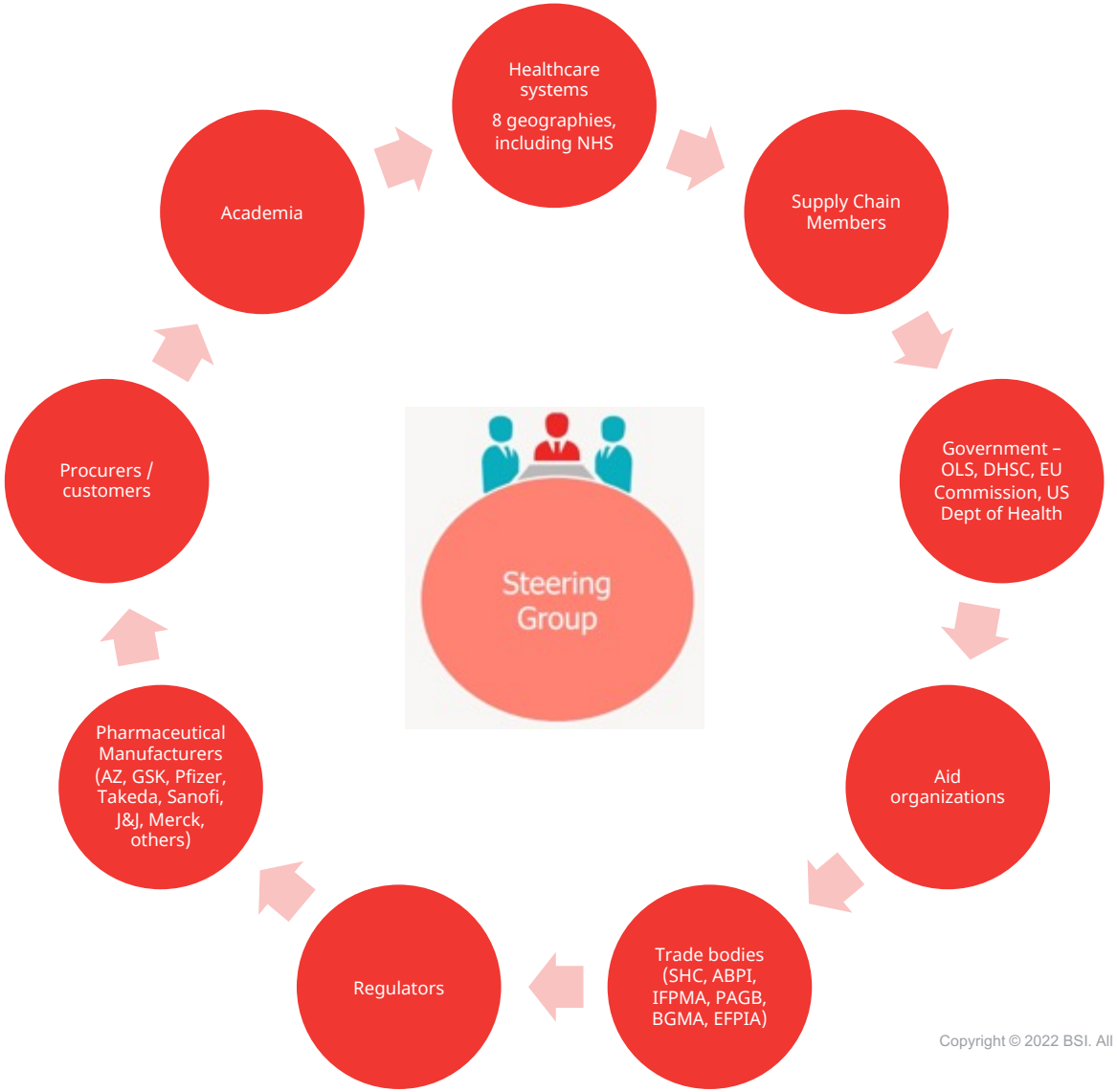
Consensus communities comprises:

- Typically 10 to 15 stakeholders
- Broad range of stakeholders e.g. patients, regulators, customers, associations, academics, etc.
- Signed up to a Steering Group protocol around consensus

Responsible for:

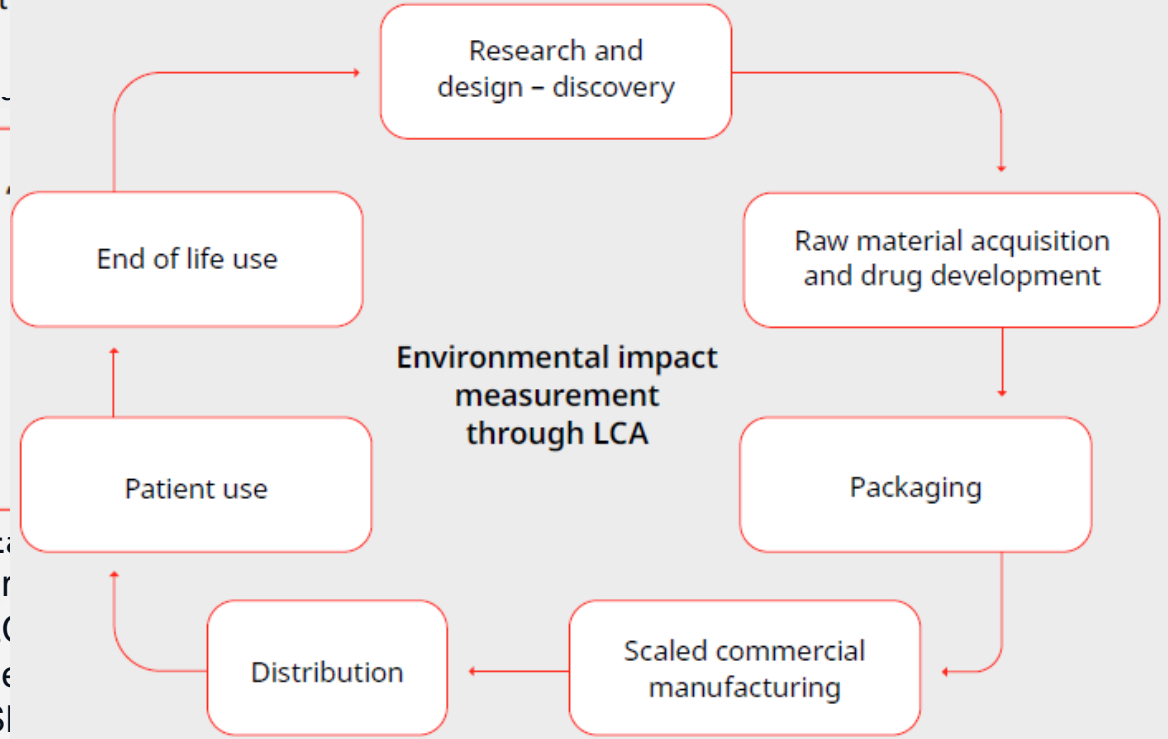
- Providing stakeholder group expertise
- Reviewing and commenting on technical drafts
- Attending Steering Group meetings
- Resolving comments , building consensus and approving drafts
- Identifying stakeholders for the Review Panel

Stakeholders convened around programme of work already



"Right now, we haven't even agreed what those data points are. A good starting point would be to list, say, 12 key categories – from emissions to process mass intensity to waste-water discharge where we know manufacturers can provide data – so at least when HCPs are starting to gather data, it's at least aro… can start

"I know we and other manufacturers are looking at this, and if they've made progress, there's a real need in the industry to share and align on them – please share it!"



efficacy of the product. We must set environmental categories with the best outcome for the patient in mind."

Manufacturer's point of view

Defining environmental impact categories and methodologies for consistent LCA data

The pharmaceutical industry has taken more seriously in recent years the approach to developing products that have focus environmental impact based on life cycle assessment (LCA) – focusing on "eco-design" R&D stage for new medicines, through towards the end of life purpose of medicines.

Manufacturers' desires

- Integrate eco-design at each stage of medicine lifecycle.
- Better enable commercial and external affairs to relay correct message, not greenwashing.
- Consistent methodology for measuring different product platforms.
- Desire to better capture data related to product environmental impact (existing and future drugs).
- LCA as an assessment technique to quantify the environmental impacts

"We may not be able to require the same level of environmental reporting for legacy medicines as we expect for new ones, but we will still want some assurance on the environmental impact of a legacy medicine."

Agreement to progress together as a healthcare ecosystem

"It varies by geography, and even by hospital procurement systems within geographies. We need to push forward together, rather than duplicate efforts, with all the extra workload that creates."

"There many people working on this in silos and coalitions – and some of them think they're in the lead. My own view is that no-one is in the lead! We're really keen to achieve some consensus and influence a standard approach. That would be way better for everyone in the industry – manufacturers and their customers."

"We need to agree with manufacturers and other industry stakeholders what the key environmental attributes should be – along with consistent measures for them."

All we want is a meaningful standard and assurance that the standard has been met. We don't really need to know all the technical details. We just need to be able to trust that there's a framework that the manufacturer is adhering to and that it's been independently verified."

"It's great that BSI has brought us together. BSI is the independent and impartial body that we can all feel comfortable to be involved with."

"As manufacturers, we should work together to inform hospital systems about where sustainable product design can lead to better environmental impact and improved LCA development."

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A unique combination of BSI statuses – role of a neutral convener

National Standards Body

- Creation and sharing of standards
- Legacy of consensus building
- Convening industry ecosystems

Convener of industry ecosystems Consensus on Expectations

Assurance Body

- Assessment / Certification
- Product Certification
- Training / Upskilling

Global auditors, understand assessment methods

Notified Body

- Acting on behalf of regulator to approved medical device safety and quality at market entry

Ability to link assessment with regulation

Consulting Body

- Sustainability, EHS, and supply chain practices

Deep SME for program governance & vendor improvements

Not-for-profit distribution, Global, Royal Charter

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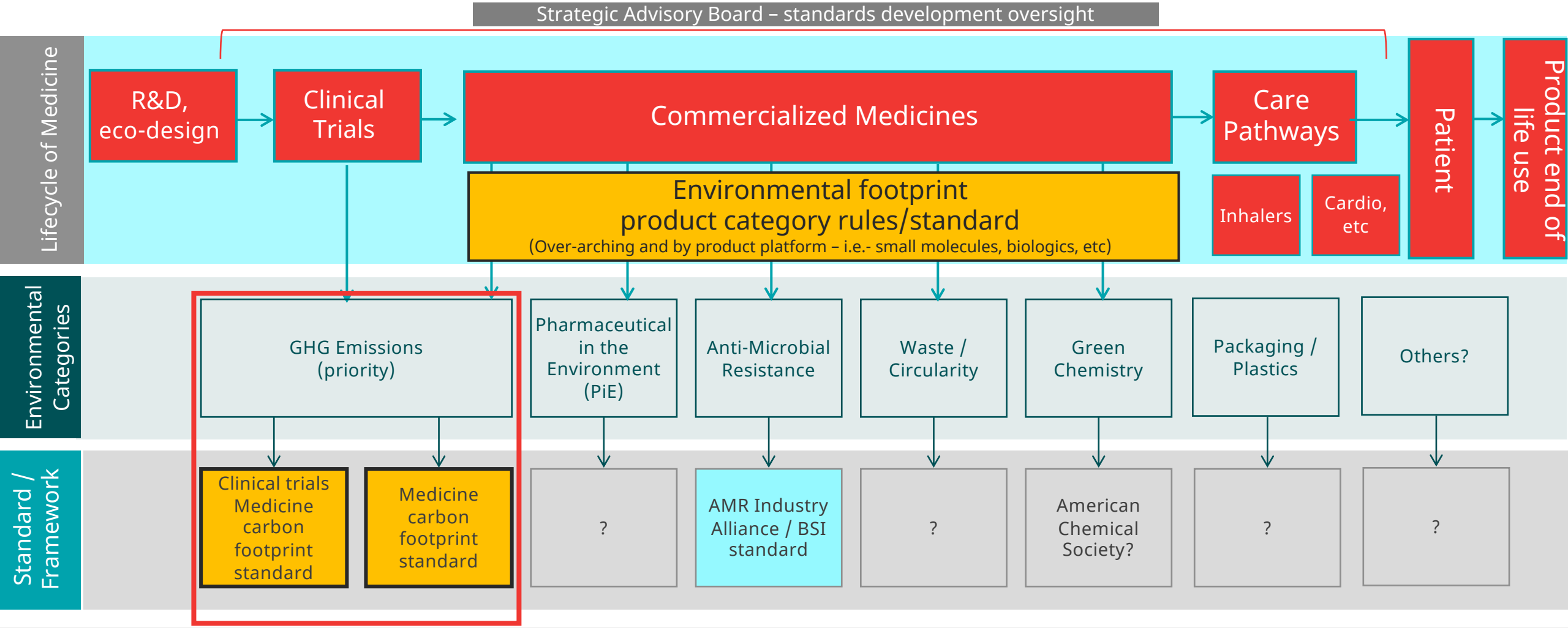

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Standard complete

BSI convening Standard scoping in progress

Express interest in learning more or participating

Register interest in stay informed of progress in this workshop