Snakebite Stakeholders Meeting Report

A Market Access-Oriented Social Enterprise for Snakebite Envenoming: A Model for Accelerating Access to Health Interventions for Snakebite

August 2026

Table of Contents

Executive Summary

On 16 April 2026, the Liverpool School of Tropical Medicine (LSTM) convened a one-day hybrid stakeholders meeting bringing together 46 experts across snakebite research, implementation, and investment. The purpose was to identify and explore the key market access, implementation, and financing barriers that prevent promising snakebite therapeutics and diagnostics from reaching the patients who need them most. This meeting was conducted under the Chatham House Rule to encourage open and candid dialogue. As such, the views expressed reflect the opinions and experiences of individual participants and not necessarily their respective affiliated organisations, and this report should be read as a synthesis of those discussions rather than a validated or independently verified account of all the data and claims presented.

The meeting pursued three overarching objectives:

- To identify common themes and priority barriers to delivering accessible snakebite solutions to market.
- To define and receive feedback on the concept of establishing an access-focused Snakebite Social Enterprise (SSE).
- To gather stakeholder input to refine the SSE's priority activities.

Following scene-setting presentations from LSTM, invited snakebite experts, innovators and representatives of global health product development partnerships, the day was structured around two interactive workshops. Workshop 1 examined the access bottlenecks facing antivenom treatments, novel therapeutic modalities, and diagnostics across their respective development pathways. Workshop 2 tasked participants with designing the strategic scope, vision, operating model, and theory of change for a market-access oriented SSE that could address the most critical of those challenges.

Across all three product classes, participants converged on a consistent diagnosis: technical, manufacturing, regulatory, financing and health system barriers are deeply interconnected, and market access is too often treated as a downstream concern rather than being designed into product development from the outset. Participants broadly agreed that a not-for-profit SSE could potentially address this gap. There was also strong consensus that the snakebite field lacks a dedicated actor capable of coordinating across academia, manufacturers, regulators, and funders. Again, the SSE was perceived to likely be well positioned to fill this "system integrator" role by connecting existing efforts rather than duplicating them.

This report summarises the key discussions, insights, and recommended next steps from the meeting.

LSTM gratefully acknowledges all participants for contributing their time and expertise to this meeting. Their candid insights and collaborative spirit were central to shaping the discussions and recommendations presented in this report.

Introduction

Significant scientific innovation has emerged in the snakebite field in recent years — spanning next-generation antivenoms, novel small molecule and biologic therapeutics, and rapid diagnostic tools. Yet, several persistent barriers continue to prevent these advances from achieving sustainable market uptake in the low- and middle-income country (LMIC) communities that bear the greatest burden of snakebite envenoming (SBE).

This meeting was convened by LSTM and held in Liverpool, United Kingdom, bringing together 46 snakebite stakeholders from different backgrounds (academia/research, innovators, antivenom and biologic manufacturers, funders/donors, product development partnerships, biotechnology SMEs, policy and advocacy organisations) and geographical regions (see Appendix 1 for the full participant list and the organisations they represent).

The meeting opened with welcome remarks from Professor David Lalloo, Vice-Chancellor of LSTM, Professor Nicholas Casewell, Director of LSTM's Centre for Snakebite Research and Interventions and Dr. Becky Jones-Phillips, Director of LSTM's Enterprise and Innovation Department.

Thereafter, a scene setting presentation was delivered by LSTM's Dr. Ezekiel Boro and Dr. Ini Umoh, followed by exemplars of different in-development innovations in the snakebite space, specifically conventional antivenoms (Dr. David Williams, ***World Health Organization***), recombinant antibodies (Professor Andreas Hougaard Laustsen-Kiel, ***Technical University of Denmark***), oral small molecule drugs (Dr. Tim Platts-Mills, ***Ophirex***) and diagnostic tests (Dr. Soumya Palliyil, ***Brigid Bio***). These presentations set the scene for an in-depth discussion about snakebite access challenges during the meeting's first workshop, with specific practice-based insights from developing and/or implementing snakebite therapeutics (antivenoms, small molecules, biologics) and diagnostics. To further aid the discussion, representatives from global health product development partnerships (Dr. Scott Knackstedt, ***PATH***; Dr. Isabela Ribeiro, ***DNDi***) delivered presentations providing insights from developing and introducing new interventions for other global health diseases.

Following completion of the first workshop, attendees received a presentation from LSTM's Aaron Argomandkhah and Dr. Carolina Velasco introducing the concept of an access-oriented snakebite social enterprise, which was followed by a second in depth workshop to critically review the strategic focus, vision and mission, and operating and

theory of change models for this social enterprise using case studies drawn from antivenom, therapeutic and diagnostic product development scenarios.

The full agenda from the day is provided in Appendix 2.

Workshop 1: Identifying Snakebite Access Bottlenecks

In-person participants were divided into three breakout groups, with online attendees forming a fourth, and each group was assigned a scenario-based case study focused on one of three snakebite product classes (conventional antivenoms, novel therapeutic modalities, and diagnostics). Each group was asked to map barriers and bottlenecks across the theoretical product's translational pathway, explore the underlying root causes to these barriers and bottlenecks, identify the most critical challenges, and capture initial ideas for addressing them.

While the groups worked from product-specific case studies, the barriers they identified were deeply interconnected across all three product classes. This section therefore synthesises their findings thematically, drawing out where challenges are shared and where they are specific to a particular modality.

Technical (Preclinical and Scientific)

Technical and scientific limitations affect the development of all three product classes, though they are particularly acute for antivenoms, where preclinical models have historically driven regulatory approvals and in-country use.

Antivenoms

There is a mismatch between preclinical laboratory testing and real-world clinical use, as current animal models for antivenom testing do not typically reflect real-world clinical scenarios[1]. Venom and treatment are often co-incubated and co-administered in model systems, while in clinical practice patients receive antivenom after envenoming. Preclinical antivenom efficacy is also commonly measured by animal survival alone, which in many cases does not translate reliably to effective dose predictions or clinical outcomes. Another overlooked but important variable is the geographical variability of venoms: even within the same snake species in the same country, venom composition can vary significantly and impact efficacy, yet this is rarely evaluated by antivenom manufacturers[2]. The World Health Organization (WHO) guidance for standardizing

[1] Ainsworth S, Casewell NR, Sartim MA, Marriott AE, Gutiérrez JM. Animal models in venom and antivenom research: The need to align academic discovery with manufacturing and regulatory expectations. *PLOS Neglected Tropical Diseases*. 2026;20(7):e0014537. doi:10.1371/journal.pntd.0014537

[2] Ainsworth S, Menzies SK, Casewell NR, Harrison RA. An analysis of preclinical efficacy testing of antivenoms for sub-Saharan Africa: Inadequate independent scrutiny and poor-quality reporting are

preclinical models, while important for global consistency, require updating to better reflect progress in this space. There is also a need for better alignment between Quality Control (QC) models used in manufacturing and those used at the preclinical developmental stage. The consequences of these deficiencies are that antivenom treatments that appear effective in preclinical models often fail in later stages, reflecting a persistent disconnect between preclinical efficacy models, rescue models, and the biomarker and pathology markers that would best support regional translation. This is particularly pertinent because most antivenoms have been approved for human use based on animal data, without robust evaluation in clinical trials.

Novel Therapeutics

The development of novel therapeutics must align with clearly defined Target Product Profiles (TPPs)[3]. TPPs should be treated as living documents, updated at least annually to reflect new data, the changing competitive landscape, and evolving regulatory expectations. Central questions to resolve at the outset include whether existing data on repurposed compounds supports reaching the target TPP; how data from early studies informs both the TPP and the preclinical package; and what short-, medium- and long-term product goals look like. Safety data is a particularly significant milestone for novel therapeutics. Accessing the clinical data needed for repurposed molecules requires lengthy negotiation with originator pharmaceutical companies, but this data is valuable for de-risking development. Early consideration of chemistry, manufacturing and controls (CMC) requirements, including active pharmaceutical ingredient (API) production, scalability, and cost of goods is essential for all small molecule therapeutics. For novel biologics, the generation of safety data is an unavoidable critical step that will require appropriate resourcing, while cost-effective manufacturing processes will need to be appropriately scaled. More generally, the cost of scaling up for good manufacturing practices (GMP) manufacture required for clinical trials in diverse geographical settings remains a significant barrier.

Diagnostics

For diagnostics, the absence of a gold standard benchmark and the history of misclassified products have created a technical credibility gap that makes it difficult for any new product to gain regulators' confidence. Investment in establishing minimum standards and reference materials is a prerequisite for restoring trust and enabling the development of a reliable product pipeline.

---

barriers to improving snakebite treatment and management. *PLOS Neglected Tropical Diseases*. 2020;14(8):e0008579. doi:10.1371/journal.pntd.0008579

[3] World Health Organization. Target product profiles for snakebite treatments. https://www.who.int/teams/control-of-neglected-tropical-diseases/snakebite-envenoming/target-product-profiles

Manufacturing

Manufacturing constraints affect all three product classes, though some specific issues may be unique to each modality.

Antivenoms

For antivenoms, manufacturers face a combination of technical and commercial pressures. As mentioned, deficits in preclinical models exist and QC models used in manufacturing can differ significantly from those used at the preclinical stage, creating inconsistencies that compound across the pipeline. Unrealistic price expectations place further pressure on quality: a manufacturer may be asked to supply antivenom at USD 5 per vial while their cost base requires USD 300. Furthermore, the absence of QA/QC standards and limited post-market surveillance capacity in many LMICs create conditions in which poorly manufactured products can enter and distort the market.

Novel Therapeutics

The core manufacturing challenge for novel therapeutics is the cost and complexity of establishing GMP production particularly for antibody-based modalities, where a minimum of several million USD is required to establish manufacturing infrastructure, compared to hundreds of thousands for small molecule GMP batches at some facilities. Antibody manufacturing does benefit from well-established, standardised upstream and downstream processes, making production more predictable once established, but the upfront investment is substantial and such facilities are rare in LMIC settings that suffer the greatest burden of snakebite. Critically, this translational manufacturing phase tends to attract less investor interest than early R&D or clinical trials, despite being essential to progression. Contract Development and Manufacturing Organisations (CDMOs) can perform scale-up and technology transfer to regional manufacturers, and Brazil's Instituto Butantan was cited as a promising CDMO partner model.

Diagnostics

For diagnostics, manufacturing capacity is very limited and often inefficient, leading to high costs for end products. The absence of QA/QC standards and a lack of regulatory benchmarks create conditions in which poorly manufactured or misclassified products enter the market, eroding clinical trust and deterring adoption. Process innovation linked to external research was identified as a priority to reduce costs of goods.

Across all three product classes, participants highlighted a structural geographic inequity, with many endemic regions where products are needed lacking manufacturing capacity (this is particularly noticeable in sub-Saharan Africa), representing a long-term vulnerability. Given current geopolitical instability, building regional manufacturing capacity was seen as essential for health system independence. Multi-product regional facilities are more investable and would better serve local needs but will require local IP frameworks and advocacy to justify the required investment.

Regulatory

Regulatory challenges were among the most consistently raised barriers across all three product classes, and were characterised by a combination of insufficient guidance, fragmented systems, and weak institutional capacity in key markets.

Antivenoms and Novel Therapeutics

Although WHO guidelines have provided important global standardisation for risk-benefit assessment[4], significant limitations persist for antivenoms. These limitations include cumbersome and expensive regulatory approval and market authorisation processes across 55 territories in Africa; varied lethality testing requirements, which are in some cases not feasible. Also, national or regional post-market surveillance capacity remains limited in many LMICs.

For novel therapeutics, selecting the correct regulatory-approved animal models is particularly challenging, and the divergence of requirements across countries adds significant cost and complexity, especially where different models are mandated in different jurisdictions. Early engagement with regulators was strongly recommended, particularly in regions where the regulatory environment is fragmented. With more complex venoms, antibody CMC and regulatory approval will become progressively more difficult.

A recurring concern across antivenom and novel therapeutics was the inadequate regulatory understanding of snakebite-specific interventions. Regulators and policymakers frequently lack sufficient knowledge of snakebite therapies, leading to approval decisions that do not reflect clinical reality. For example, misinterpretation of appropriate dosing regimens or failure to distinguish snakebite treatments from standard generics. Underdosing was flagged as more prevalent and dangerous than overdosing, making targeted education of regulators and healthcare professionals an urgent priority.

Diagnostics

For diagnostics, the regulatory situation is especially acute. There is no established pathway for rapid snakebite diagnostics, no gold standard against which products can be benchmarked, and no globally, regionally, or nationally recognised authority responsible for overseeing minimum requirements or standards. This creates a self-reinforcing problem: clinical trial data is needed for regulatory approval, but ethical committee approval for trials is difficult to secure without pre-existing standards. This cycle prevents diagnostic technologies from progressing beyond Technology Readiness Level 4/5 and ultimately blocks patient access.

[4] World Health Organization. Antivenom Risk-Benefit Assessment Procedure. WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control). https://extranet.who.int/prequal/vaccines/antivenom-risk-benefit-assessment-procedure

Across all product classes, the African Medicines Agency (AMA) was identified as having significant untapped potential to play a central coordinating regulatory role across the African continent, where many deficiencies are pronounced. Some participants identified Nigeria and Kenya as potentially accessible entry markets in Africa for piloting technologies, with the potential for diffusion across the region leveraging existing research relationships. Stronger advocacy from in-country organisations rather than external voices was seen as essential to influencing policy and co-creating new treatment protocols, and the U.S. Food and Drug Administration (FDA) "animal rule" was also highlighted as a useful comparator for navigating approval pathways more broadly.

Intellectual Property

IP protection was discussed primarily in the context of novel therapeutics, though the issues raised have relevance across the field. The core challenge is that IP frameworks are highly context-dependent, and the conventional assumption that strong IP protection drives investment and development does not hold uniformly.

In many African countries, limited IP infrastructure means innovators struggle to secure and maintain patents, reducing their leverage to attract investment in GMP manufacturing. The group debated whether IP protection is always necessary, noting that in some contexts open innovation may be more effective at accelerating product development. Some participants noted that appropriate IP protection may remain necessary to attract investment and sustain long-term product development while enabling equitable access. IP is not always necessary, but something must substitute for it: donor capital, procurement commitment, regulatory exclusivity, manufacturing know-how, brand/quality differentiation, WHO prequalification, product development partnership sponsorship, advance demand, or public-sector ownership.

A nuanced example from India illustrated how IP can serve an unconventional purpose: a company sought patent protection not primarily for commercial reasons but to secure a high-quality local manufacturer. Regulators indicated they would be more likely to support a patent application if local manufacturing could be demonstrated – creating a situation in which IP was a prerequisite for quality assurance, rather than for exclusivity. The broader observation was that without a guarantee of who will purchase an innovation, institutions lack the leverage to justify the cost of securing and maintaining IP.

Financing and Value Proposition

Across all three product classes, the fundamental financing challenge is the same: the snakebite market is too small, too fragmented, and too poorly characterised to generate the predictable commercial returns that would attract private investment at scale.

Making the case for investment to both commercial actors and governments requires a stronger and more evidenced value proposition than currently exists.

Antivenoms

The antivenom market is structurally unreliable and unpredictable, which is partly attributable to reactive procurement and based on approximation rather than robust demand data. This challenge is further exacerbated by poor integration of antivenom supply into national procurement systems. There was consensus on the need for a comprehensive total cost model that captures not just product costs but the downstream costs of delayed access, including ICU and hospital stay expenditure, lost productivity, and long-term disability. The Latin American model of regional stockpiling was cited as a positive example of how to create a more reliable and investable market.

Novel Therapeutics

Although it is very hard to find investors for snakebite therapies, including small molecules, this therapeutic modality does have two advantages that are worth noting. First, small molecules typically have a much lower cost of goods than biologics, so can be priced competitively and still generate revenue in commercial markets (and very cheaply and compatible with global public health priorities in LMICs). Second, the small molecules that are currently the focus of snakebite therapeutic development work are inhibitors of toxins found in venoms across the globe, so these solutions have the potential to work in many different markets, which is important in terms of recovering the cost of development.

Diagnostics

Health financing reimbursement systems for diagnostic products are poor or absent in resource-limited settings, leaving the market almost entirely reliant on donor and philanthropic funding. Without clarity on who is responsible for purchasing snakebite diagnostics, and without demonstrated demand, manufacturers have little incentive to invest in production. Participants highlighted the potential for private healthcare systems to act as an initial entry point drawing on the example of PATH's introduction of contraceptive devices in Africa via private channels before achieving state-funded rollout as a model for creating initial demand and building the evidence base for broader adoption.

Across all modalities, participants emphasised the importance of demonstrating economic value in terms that resonate with governments – not just health outcomes, but job creation, supply chain development, and broader economic returns. Countries will need concrete, evidence-based business cases and not just efficacy data to justify investment in snakebite interventions.

Market Access

Market access was identified as a structural gap common to all three product classes and, crucially, one that is too often treated as a downstream concern rather than a design principle. The overarching message from participants was that market access cannot be retrofitted at the end of a development programme; it must be built in from the outset.

For all product classes, researchers and developers tend to focus on scientific and trial milestones, partly because dedicated market access expertise and funding are difficult to secure. This leaves critical questions – around pricing, procurement channels, regulatory pathways, health system integration, and demand generation – unanswered until late in development, when they are far more costly to address.

Antivenoms

For antivenoms, the unreliable and unpredictable market is itself a barrier: without a clearer demand signal and more stable procurement environment, commercial manufacturers lack the incentive to invest in capacity or quality improvements. Strengthening market intelligence through centralised systems capturing data on market need, preclinical demand, and clinical usage was identified as an important lever. Currently, reliable market data only emerges at the clinical trial or product registration stage, by which point many strategic decisions have already been made.

Novel Therapeutics

Market access challenges are compounded by the absence of a clear reimbursement pathway and the need to build the economic case to governments who may be weighing snakebite interventions against many competing health priorities. Participants called for robust cost-benefit analyses that demonstrate not just efficacy but economic value: contributions to job creation, supply chain development, and longer-term healthcare savings. Africa's more fragmented regulatory environment relative to other markets with more centralised structures adds further complexity for developers seeking to access multiple markets.

Diagnostics

For diagnostics, the market access challenge is particularly acute because demand must be created: governments and health systems need to be convinced that diagnostics are necessary when they already have antivenom as a treatment. Demonstrating the economic burden of dry bites, misdiagnosis, and inappropriate antivenom use and translating that into a cost-saving argument is central to any viable market access strategy. Health economics studies and decision-support tools were identified as critical enablers.

The central unresolved structural question – who is ultimately responsible for aligning R&D, academia, funding, policy, and market access across the snakebite field – was raised but not resolved and was itself identified as a gap that a dedicated entity such as

the proposed SSE might be positioned to address. Examples of genuinely coordinated approaches in the snakebite space remain limited; the 100 Days Mission framework from pandemic preparedness was cited as a model worth exploring as a reference point for more structured field-wide coordination.

Health Systems

Health system challenges represent a cross-cutting category that affects the uptake and impact of all three products and are closely linked to the data and evidence gaps discussed below.

A fundamental issue is that snakebite lacks clear institutional ownership within national health systems in many endemic countries. There are ongoing political misalignment and lack of consensus on whether snakebite should be classified as a "disease" or an "incident", which contributes to its systematic deprioritisation in national health strategies. This is compounded by the fact that, unlike most other WHO-priority neglected tropical diseases (NTDs), snakebite is non-infectious and episodic, making it harder to integrate into existing disease-focused frameworks.

Procurement systems are a particular weakness. Procurement is frequently reactive, based on guesswork rather than reliable demand data, which leads to both under- and over-supply, distorts demand signals to manufacturers, and makes it difficult to build the business case for investment. Sub-optimal antivenom management, including procurement of too many doses in some settings, can paradoxically signal to governments that there is no unmet need, depressing the political priority assigned to the issue.

Clinical management practices vary enormously and are often sub-optimal. In primary care facilities, especially in rural settings, healthcare workers may lack the clinical skills to accurately diagnose and treat snakebite, leading to inappropriate antivenom administration. In state hospitals, clinicians may delay treatment until symptoms appear (due to the cost of each dose and the high incidence of dry bites), risking preventable morbidity and mortality. In some settings, financial incentives may contribute to variation in treatment practices. . The development of regionally appropriate clinical decision-support tools was identified as a priority for improving healthcare worker practice and system readiness.

In some high-burden countries, particularly in Africa, clinical management is further complicated by specific contextual factors. For example, in some settings medical staff are instructed to wait 6–10 hours before administering antivenom to pregnant women due to unclear guidance on risks to the foetus - a situation where effective diagnostics could significantly improve care. The lack of genus-level diagnostics in Africa also means that available monovalent antivenoms are often not deployed optimally.

Strengthening health systems, improving national supply chain integration, and elevating SBE onto national and regional agendas with strong champions at all levels of government were identified as foundational requirements to underpin progress across all other barrier categories.

Workshop 2: Designing an Access-oriented Snakebite Social Enterprise (SSE)

Working in the same groups from the first workshop, participants were asked to design the key components of an access-oriented SSE based on three case study scenarios built around antivenom, novel therapeutic and diagnostic snakebite product classes.

Each group was tasked with answering the following questions:

1. Strategic Scope and Focus

- What specific access barriers (e.g. affordability, availability, distribution, quality assurance, demand, provider training) does the SSE need to prioritise to successfully aid adoption and implementation of the product?
- Should the SSE focus on specific markets or have a broader geographical focus?
- How will the SSE complement (rather than duplicate) existing/similar global health efforts by other organisations to achieve the same goals/objectives?

2. Vision and Mission

- Does the proposed vision and mission align with the on-the-ground realities of snakebite incidence, and the innovation challenges it is seeking to overcome; who are its primary beneficiaries?

3. Operating Model and Governance

Map out and prioritise a high-level model that the SSE should take-on, covering:

- Core services
- Pricing and funding strategies
- Business and operational model
- Governance structure

Demonstrate how the model will:

- Reduce financial and geographic barriers to the product's access

- Ensure supply reliability and quality
- Align with national regulatory and health system constraints

4. Theory of Change/Logic Model

Develop a theory of change/logic model that links:

- Inputs and activities
- Outputs
- Short and long-term outcomes
- Impact

1. Strategic Scope and Focus of an access-oriented SSE

The consensus across all participant groups is that the SSE should function as a *system integrator and ecosystem coordinator*. A dedicated venture such as this would add value to the ecosystem as a strategically positioned **"connector"** that orchestrates the journey from discovery to clinical implementation. This approach addresses the "Valley of Death" where high-potential innovations stall due to fragmented value chains, misaligned commercial incentives, and a lack of dedicated translational support.

The SSE should provide specialised support through core market access modules, which should include country prioritisation considerations to target the most permissible implementation environment, usability feedback from key stakeholders, and regulatory and manufacturing landscaping, alongside engagement and coordination activities.

A key function will be coordinating **"handoffs"** during critical development progression points, ensuring that transitions are managed with a bigger picture/implementation-focused lens. Crucially, the SSE *must fill gaps* and act as a conduit between actors, such as academic laboratories; manufacturers; and non-governmental organisations (NGOs), rather than duplicating existing efforts. Participants emphasised that the SSE must remain flexible and **technology-agnostic**, capable of supporting a diverse pipeline of assets, including small molecules, antibodies, and diagnostics, to ensure long-term operational sustainability.

- **Antivenoms:** The focus is on commercialising high-efficacy products and addressing the research-to-market stall caused by in-country regulatory bottlenecks. Key takeaways include the possibility of facilitating direct procurement to reduce intermediary price markups and control final pricing for Ministries of Health.
- **Novel Therapeutics:** Strategies centre on repurposing established drugs to provide a paradigm shift in pre-hospital care for haemotoxic envenoming. Access

requires focusing on safety data for new indications and ensuring pre-hospital stability for community-level deployment.

- **Diagnostics:** The scope is defined by the need for rapid, reliable triage tools as low-cost tools to guide clinical decision-making. These must concentrate on demonstrating the economic burden of "dry bites" and misdiagnosis, and the cost saving of antivenom and/or reducing total cost to the health system to drive adoption.

2. Vision and Mission

The SSE's proposed mission is rooted in the WHO's roadmap goal[5] to *halve snakebite deaths and disabilities by 2030*. Participants agreed that the enterprise must be an impact-first organisation, measuring success through health equity and capacity building alongside financial viability. The vision addresses the reality that snakebite disproportionately affects the world's most vulnerable populations: rural labourers, children, and those in regions with the weakest health systems.

The mission is not only to provide products to market, but to strengthen health systems by embedding snakebite within existing NTD and national health frameworks rather than creating parallel systems. It was highlighted that while snakebite is a WHO-priority NTD, it differs from other NTDs as it is not infectious and often lacks a clear identity or local engagement. The SSE should aim to elevate the profile of snakebite and remove the associated stigma through coordinated advocacy, though this may overlap with other groups.

> ***Antivenoms:*** *The mission is to ensure a reliable, affordable supply that reduces health expenditure and prevents more deaths and disability-adjusted life years (DALYs). Supply chain reliability is the primary driver here.*
>
> ***Novel Therapeutics:*** *The mission is to facilitate the launch and integration of new therapies that can either supplement or improve traditional antivenom and can be deployed at the community level to facilitate rapid treatment and expand the "window of care".*
>
> ***Diagnostics:*** *Success is defined by tools that allow triage at a community level, reducing the high incidence of anaphylaxis caused by unnecessary antivenom administration, thereby safeguarding both patient health and medicine supply.*

3. Operating Model and Governance

The SSE is proposed as a **sustainable, hybrid, not-for-profit social enterprise**. Unlike a time-bound consortium, this structure would allow the enterprise to reinvest profits,

[5] World Health Organization. Snakebite envenoming -- A strategy for prevention and control. 2019. https://www.who.int/publications/i/item/9789241515641

accept donor grants, and raise impact investment while safeguarding its public-good mission.

A sensible approach comprises an initial "lean model" operating phase, potentially employing a single Commercialisation/Access Manager seconded from LSTM to establish a proof-of-concept. As it scales, the enterprise could provide quick-turnaround services via a fee-for-service consultancy model and/or subscription model/service to generate revenue, supplemented by philanthropic seed funding. Governance must include a Community Board with lived experience to ensure advocacy remains authentic and rooted in the needs of affected countries.

Core Service Offerings

Activity should be offered on a case-by-case basis and include signposting and engagement with regulators and manufacturing partners. The SSE should provide standard pricing packages containing essential materials, such as country prioritisation data, with transparent consultancy fees.

Knowledge and Networking

A major value proposition is the creation of networking opportunities with collaborators, investors, and regulators. This includes sharing knowledge, information, and lessons learned regarding potential bottlenecks to tackle emerging issues more effectively.

In-Country Expertise

Participants emphasised that the SSE should avoid becoming a UK-led entity insufficiently grounded in endemic-country priorities and leadership. The SSE therefore requires in-country expertise to navigate national policies and access local regulators in key regions such as South Asia and Africa. Once the SSE is established, forming a global south regional or in-country presence or affiliation with an existing PDP's global south office (e.g., DNDi India or Kenya) was proposed as one potential way to mitigate against this.

4. Theory of Change and Logic Model

The **Theory of Change (ToC)** provides a roadmap linking technical inputs to global health impact. Success is defined as the establishment of a robust, de-risked pipeline that delivers accessible, affordable snakebite interventions to priority LMICs.

Category	**Core Components**
Inputs	LSTM technical expertise, global snakebite network, strategic partnerships with WHO and NGOs, and initial seed funding.

Activities	Execution of market access modules, intellectual property rights management, active political advocacy, and coordination of development handoffs.
Outputs	Mapped regulatory pathways, equitable licensing agreements, and a repository of manufacturing feasibility reports.
Outcomes	The key short- and long-term outcomes are: **Short-term:** Launch of 1–2 market-ready products and established proof-of-concept for SSE. **Long-term:** Regional self-sufficiency, reduced snakebite morbidity and mortality, and replicable cost-benefit blueprints. Other additional product-specific outcomes include: ***Antivenoms:*** *Outcomes include informed procurement strategies, improved product availability and reduced catastrophic out-of-pocket health expenditure.* ***Novel Therapeutics:*** *Outcomes focus on successful technology transfer to LMIC manufacturers, scale-up, and the progression of assets through technology readiness levels.* ***Diagnostics:*** *Improved patient health outcomes through faster triage and better clinical management, measured by antivenom cost savings, early therapeutic intervention and reduced DALYs.*

5. Key Risks and Mitigation Strategies

Participants identified critical vulnerabilities that could lead to enterprise failure, from political misalignment to the risk of an insufficient customer base to maintain sustainability.

Market Entry Strategy: A key recommendation is to identify and prioritise markets where products can more easily get through to market and where health professional and patient uptake is most likely, rather than solely focusing on the highest disease burden settings. Getting products to market quickly in regions amenable to product registration would allow the SSE to establish success and credibility before expanding into areas where regulatory hurdles are more challenging. This should be a key consideration and criteria within the proposed country prioritisation activity.

LMIC Regulatory Capacity: A major risk is the lack of capacity or delayed timelines within LMIC national regulatory agencies.

- **Mitigation:** The SSE should act as a regulatory broker, with a heavy reliance on **WHO-Listed Authority reliance pathways** and WHO risk-benefit channels where available to fast-track innovation.

Political and Advocacy Risks: Resistance from local policymakers who prioritise lowest-unit-cost procurement tenders over high-quality differentiated products.

- **Mitigation:** Work to shift the investment case framing from unit cost to the total cost of care, demonstrating savings from reduced duration of hospital stay and prevented disabilities through coordinated economic impact assessments.

Operational Integrity and Reputational risk: The risk of mission drift or providing low-quality advisory services could be reputationally damaging.

- **Mitigations:** Implement a quality control framework and steering committee/governance model, comprised of cross-discipline and cross-sector members. Maintain low overheads. Utilise local consultants to ensure context-specific expertise.

Modality Specific risks

Antivenoms face the risk of market distortion if novel supply chains destabilise existing providers.

Novel Therapeutics carry high attrition rates, particularly for small molecules.

Diagnostics face the risk that species variation across regions makes a single generic solution ineffective, while impacting upon antivenom use requires robust integration into clinical practice.

Recommendations and Next Steps

These recommendations reflect ideas generated during meeting discussions and should not be interpreted as formal recommendations endorsed by all participants.

SSE Led Activity

Wider ecosystem co-ordination

- Convene a network drawn from meeting participants and other interested/key stakeholders to sustain momentum and align efforts.
- Build a unified voice — with potential for the SSE to act as a convenor e.g., to convene region-specific discussions for aligning regulators and other key stakeholders.

Strengthen the evidence-base and engage local organisations and communities to drive stronger advocacy

- Conduct and fund comprehensive burden-of-disease studies, health economics analyses and develop case studies to demonstrate the health and economic impact of poorly manufactured snakebite products, delayed treatment, inappropriate antivenom use, long-term disability and catastrophic household expenditure and how these erode trust in clinical settings (with patients and health workers) and regulatory and policymaking settings (with regulators and governments).
- Identify in-country/regional champions who can make the investment case to government stakeholders.
- Invest in new R&D and process innovation to improve and lower cost of goods for snakebite manufacturing. This would be a later stage activity for the SSE, as it scales.

Engage key regional agencies early and directly and drive regional regulatory alignment

- Define clear R&D and manufacturing regulatory pathways, frameworks and standards for snakebite products and position key regional regulatory agencies, such as the **African Medicines Agency (AMA),** to collaborate with other stringent regulators, such as the U.S. FDA and Europe's EMA. For instance, the U.S. FDA's "animal rule" was highlighted as a useful comparator and exemplar regulatory pathway for de-risking snakebite R&D products.

Prioritise practical, scalable solutions

- Develop simple, adaptable frameworks that endemic countries can implement with existing resources, enabling near-term progress alongside longer systemic change.

Adapt pandemic preparedness models

- Explore how the 100 Days Mission and Global Preparedness Monitoring Board's approach to setting measurable milestones, ensuring pipeline visibility, and driving stronger coordination and accountability for pandemic preparedness, could be adapted to accelerate snakebite R&D coordination, and response timelines.

SSE Facilitated Activity, Delivered by the Community

Strengthen the evidence-base and engage local organisations and communities to drive stronger advocacy

- Ensure stronger advocacy collaborations with local organisations and communities in affected regions. Future advocacy activities should endeavour to include more in-country or regional actors to leverage the wider social capital and network needed to influence policy change.

Engage key regional agencies early and directly and drive regional regulatory alignment

- Co-ordinate messaging and policies across regulators to ensure alignment and wider dissemination across all key stakeholders.

Integrate snakebite into existing health systems

- Embed snakebite within NTD and national health frameworks rather than creating parallel systems. Draw on models from analogous programmes such as rabies and GAVI integration.

Strengthen surveillance and data systems

- Invest in or align with existing notifiable global, regional or national disease reporting systems to improve data collection, analysis, and evidence-based decision-making.

Appendix 1: List of Participants and their Organisations

Name	Organisation	Format
Aaron Argomandkhah	LSTM, UK	In person
Andreas Hougaard Laustsen-Kiel	Technical University of Denmark, Denmark	In person
Andy Porter	Scottish Biologics Facility, UK	In person
Becky Bavinger	Bloomberg Philanthropies, USA	Online
Becky Jones-Phillips	LSTM, UK	In person
Brent Thomas	LSTM, UK	In person
Carly Davies	LSTM, UK	Online
Carolina Velasco	LSTM, UK	In person
Cassandra Modahl	LSTM, UK	In person
Celine Aerts	Impact Global Health, Australia	Online
Chloe Vasquez	Global Snakebite Initiative, USA	Online
David Lalloo	LSTM, UK	In person
David Williams	World Health Organization, Switzerland	Online
Devin Sok	Global Health Investment Corporation, USA	Online
Dileepa Ediriweera	LSTM, UK	In person
Ezekiel Boro	LSTM, UK	In person
Frank Tianyi	LSTM, UK	In person
George Adinoh	Kenyan Institute of Primate Research, Kenya	In person
Giancarlo Biagini	LSTM, UK	In person
Guillermo Leon	Instituto Clodomiro Picado, Costa Rica	In person
Ian Cameron	MicroPharm, UK	In person
Ini Umoh	LSTM, UK	In person
Isabela Ribeiro	Drugs for Neglected Diseases initiative (DNDi), Switzerland	In person
John Amuasi	Kumasi Centre for Collaborative Research, Ghana	In person
Jose Maria Gutierrez	Instituto Clodomiro Picado, Costa Rica	Online
Joy Kumar Chakma	Indian Council of Medical Research, India	Online
Juliette Borri	Independent Consultant, Switzerland	In person
Kartik Sunagar	Indian Institute of Science (IISc), India	Online
Kurt Wibmer	University of Cape Town, South Africa	In person
Kushboo Daga	Vins Bioproducts Limited, India	Online
Laura Albulescu	LSTM, UK	In person
Marco Vigilato	Pan American Health Organisation, Brazil	Online
Michaelene Welsh	Global Snakebite Taskforce, UK	In person
Nicholas Casewell	LSTM, UK	In person
Nitin Deshpande	Premium Serums and Vaccines Private Limited, India	In person
Sakthivel Vaiyapuri	University of Reading, UK	In person
Sarah Gwyndaf Roberts	LSTM, UK	Online
Scott Knackstedt	PATH, USA	In person
Sabastine Wakdok	Impact Global Health, Australia	In person
Sonia Osi	Market Access Africa, Switzerland	Online
Soumya Paliyill	Scottish Biologics Facility, UK	In person

Soumyadeep Bhaumik	The George Institute for Global Health, Australia	Online
Stuart Ainsworth	University of Liverpool, UK	In person
Tim Platts-Mills	Ophirex, USA	In person
Tim Reed	Health Action International, the Netherlands	Online
Ymkje Stienstra	LSTM, UK	In person

Appendix 2: Meeting Agenda

Agenda	
8.30 – 9 am	**Arrival and Registration**
9 – 9.10 am	**Welcome & Objectives** • David Lalloo, *LSTM* • Nicholas Casewell, *LSTM* • Becky Jones-Phillips, *LSTM*
9.10 – 9.25 am	**Scene setting: framing the challenge** • Ezekiel Boro & Ini Umoh, *LSTM*
9.25 – 10.15 am	**Snakebite case studies: Access challenges in practice** • David Williams, *WHO* – Challenges associated with sustainable and accessible antivenom supply • Andreas Laustsen-Kiel, *Technical University of Denmark* – Advancing nanobodies as a snakebite therapeutic • Soumya Palliyil, *Brigid Bio* – Bringing a novel snakebite diagnostic to market • Tim Platts-Mills, *Ophirex* – Market access pathways for repurposed snakebite drugs
10.15 – 10.45 am	**Challenges and insights from other global health indications** • Scott Knackstedt, *PATH* – Experiences and perspectives from PATH • Isabela Ribeiro, *DNDi* – Experiences and perspectives from DNDi
10.45 – 11.15 am	**Break**
11.15 am – 12:15 pm	**Workshop 1 – Identifying Bottlenecks** • Ezekiel Boro, *LSTM* Breakout groups will: • Identify key barriers and bottlenecks across the translation pathway • Explore underlying causes • Highlight priority challenges • Capture initial solution ideas
12.15 – 1 pm	**Consolidating the problem – Workshop 1 Group feedback** • Ezekiel Boro, *LSTM*

	• Identification of common themes and priority barriers
1 – 2 pm	**Lunch**
2 – 2:30 pm	**Introducing the concept of the snakebite social enterprise** • Becky Jones-Phillips, Nicholas Casewell, Carolina Velasco, Aaron Argomandkhah, *LSTM*
2.30 – 3:30 pm	**Workshop 2 – Designing an Access-oriented Snakebite Social Enterprise (SSE)** • Aaron Argomandkhah and Carolina Velasco, *LSTM* Breakout groups will develop key components of an access-oriented SSE, including: • Scope and strategic focus • Long-term vision/mission • Operating model and governance • Theory of change/logic model
3.30 – 4 pm	**Break**
4 – 4:45 pm	**Consolidating the model – Workshop 2 Group feedback** • Aaron Argomandkhah and Carolina Velasco, *LSTM* • Group feedback • Refinement of the social enterprise concept
4:45 – 5:30 pm	**Next steps, commitments and closing remarks** • Becky Jones-Phillips and Nicholas Casewell, *LSTM* • Summary of key outcomes • Proposed next steps • Open discussion
5.30 pm	**Close, Networking, Drinks and Dinner**