PLENARY 4

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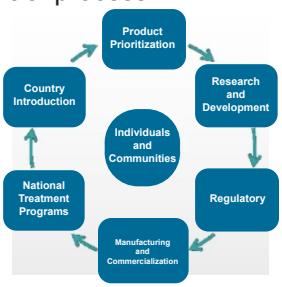
"The importance of partnerships across the continuum of care"

"Learnings from FAST-TB (how to accelerate the introduction of better TB regimens) are very relevant to what we are talking about today"

Partnerships across the continuum of care

Drug discovery, development and introduction is a complex technical, logistical, cultural and financial process.

- Timely product delivery requires a large group of diverse players.
- Academics, innovators, governments, and regulatory bodies around the world must remain coordinated and aligned for years.
- There are many opportunities to go slower – It is so much work to go faster.
- **It is our collective responsibility to ensure all voices are in the room.**

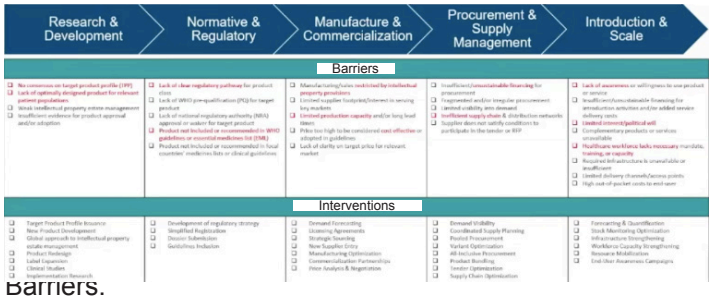


CHAI brings business acumen to global health.

- We apply learnings from any relevant discipline to:
  - ◊ Improve access to better medicines and diagnostics.
  - ◊ Tune care models in country.
  - ◊ Deliver value to the patients we serve.

Product access: Barriers, interventions, and partnerships

Overview of the product development life cycle.



Barriers.

- All the ways you can fail across the life cycle.
  - ◊ Lead to time and money poorly spent, disconnect among organizations, and misunderstandings (Language or clarity of thought).
- Highlighted challenges.
  - ◊ R&D: Lack of consensus on a TPP.
  - ◊ Normative & Regulatory: Unclear regulatory pathway.
  - ◊ Manufacture & Commercialization: Problems with IP; Limited production capacity; New product type requiring new capabilities.
  - ◊ Procurement & Supply Management: Concerns over sustainability; Fragmented supply chain.
  - ◊ Introduction & Sale: Patient population is unaware of the solution (Cure or better way to manage their disease); Variable political will.

Interventions.

- CHAI assembles expert teams to address each challenge.

Partnerships.

- Convene all parties for the conversation (Lesson learned from HIV).
- **The voice of the patient is mission critical.**
- Partners.
  - ◊ Academia.
  - ◊ Donors.
  - ◊ Industry (Innovators and generics).
  - ◊ Ministries (Discuss priorities, commitment, and political will to a disease).
  - ◊ Non governmental organizations (In-country and international role).
  - ◊ National Treatment Programs (NTPs).
  - ◊ Patients (Building strong civil societies for many diseases).
  - ◊ SRAs and normative bodies (Harmonization among FDA, EMA, WHO PQ and RAs in RLS).
  - ◊ WHO.

FAST-TB program

Overview.

- CHAI in partnership with Peter Kim.
- Convened key players across the continuum (n=50-70).
  - ◊ Designers of clinical trials for TB regimens.
  - ◊ Biomarker investigators. Improve patient monitoring during clinical trials; Understand patient position in their disease journey; Denote disease severity.
  - ◊ Modelers. Discuss better ways to model clinical trials and epidemiology in the countries we serve.
  - ◊ Various community voices: TB survivors; Civil society; and NTPs.

Learnings with particular relevance to today's meeting.

- Voice of the community is critical to better understand different aspects of the patient's journey and empower end-users to shape the research agenda.
- Inclusive subject selection goes beyond including all patient sub-populations that would benefit from a medicine/treatment.
  - ◊ The study population must inform the variability represented in the populations you serve.
  - ◊ Ensure inclusion criteria are as real-world as possible. Being too proscriptive about removing patients (i.e., Lost-to-follow-up or a particular AE) limits trial validity when translating to care in country.
    - * 'The trial does not represent how I care for patients, the patients I see, or the patient journey I see.'
    - * 'Often times the people dismissed from a trial are actually my challenge in my clinic – They are the patients I have to serve, and your trial did not help me understand how to do that.'
- Alignment, transparency and coordination between groups to ensure community voices are included across the entire journey, not only at the start.
  - ◊ This is critical for communities to attain confidence in work done on their behalf.
  - ◊ The trust needed to improve and sustain product uptake cannot be built in the absence of continuous community involvement (e.g., HIV concept, "Nothing for me without me").
- Donor and policy priorities will be addressed in another presentation.
- Market shaping. A lot of work is needed to transform care, especially with LA products.
  - ◊ A strategy for introducing a product for treatment and prevention needs to consider:
    - * What cultures are you are trying to bring a solution to? How is it you have a relationship with them?
    - * The number of patients per unit time informs the relationship or deals made with generics so that expectations are understood (i.e., Number of tablets, injections, metric tons of API, etc. per unit time).
- Person-centered care. The desire to deliver choice/personalized care is an essential mindset for success.
  - ◊ We need to better understand patient adherence challenges for LA products.
    - * LA products are going to be a boon, but they must be re-administered. The x-axis is only changing from days to months (Individuals will still need care for years)).
  - ◊ The goal of hearing what person-centered care translates into becomes very important.
    - * The story we tell, the advocacy we promote, how we wrap health care around that patient, and where that patient seeks care.
- Other relevant topics.
  - ◊ Research.
  - ◊ Diagnostics.
  - ◊ Regimen development and clinician role.
  - ◊ Product approval.
  - ◊ Product information.
  - ◊ Translation of evidence and implementation research.
  - ◊ Capacity building.