What do researchers think about Community Engagement in bNAbs trials ?

AVAC-hosted HVAD Webinar

7 June 2023

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"nothing about us without us is for us"

What researchers think about BnAbs and Community engagement …

"Lets use the bNAb wave to get research participation right: CE must be early, comprehensive, inclusive, consistent, honourable"

Community Engagement Specialist at a CRS, Johannesburg

"(bNAbs) requires the concerted efforts of all parties, including scientists, researchers, policymakers, health professionals, and community stakeholders. "

Community Engagement Specialist at a CRS, Monrovia

"I believe bNAbs are one route to finding more options to prevent HIV"

Community Engagement Specialist at a CRS, Cape Town

"bNAbs will provide insights for a vaccine discovery"

Global Advocate, Cape Town

"The right bNAbs in the right combination with the right dose, and a commercial partner who can scale up manufacturing after a highly ethical trial demonstrates efficacy and effectiveness"

Proceedings from a trial network discussion, New York

"The science behind (bNAbs) is fascinating … not sure if they would be affordable or scalable in our setting"

Investigator, Johannesburg

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What frames the researcher perspective?

- Researchers primarily draw on the Helsinki declaration, GCP standards and in varying degrees the UNAIDS/AVAC GPP guidelines
- Another influence is sponsor-driven guidance and Ethics Guidance
- And, conscience!
- "Good" Community Engagement is a challenging outcome to achieve:
  - *End state not clear -variable guidance, no standard, limited benchmarks*
  - *Contextually specific = a moving target*
  - *Limited budgets and varying commitment from sponsors*
  - *CE practices are still not yet seeing consistently identifiable RsOI*
- For bNAbs this is more challenging because the science and social context is more complex

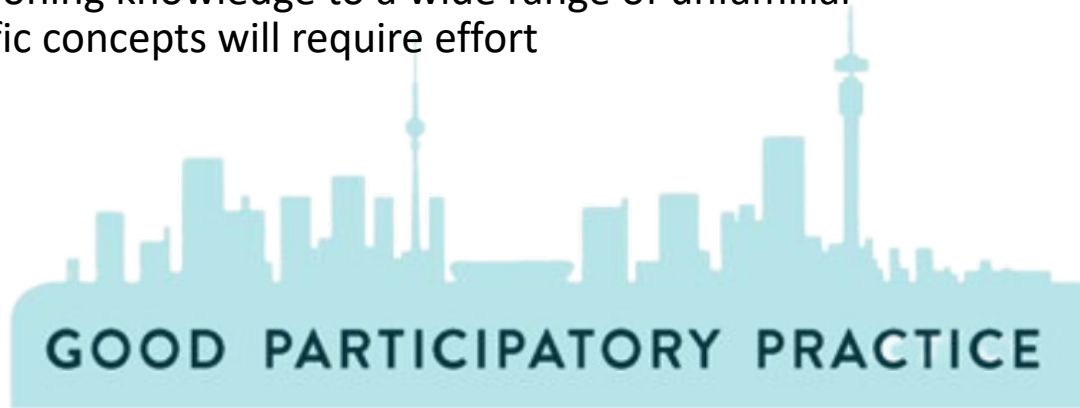
The scientific complexities of bNAbs require a more attuned community engagement focus

Considerations for sponsoring scientific leadership

- Lessons from PrEP roll-out underline the need for harmonising the clinical trial and implementation phases
- Iterative trial design is novel and will need time and languaging to muster support
- We expect advocates to demand wide applicability of vaccine candidate
- Novel delivery methods will require time to nurture acceptability
- The factor of Geopolitics: S/N Partnerships, DRM and post-trial access are the same conversation
- How do we, at the same time, sustain focus on and commitment to current HIV prevention methods ?

Considerations for on-the-ground researchers

- Community Engagement is like a marriage: it requires trust-building, patience, transparency, terms of engagement, discipline and (sometimes blind) commitment
- *"Just because you like your coffee black …"* CE will need a high degree of validating lived experiences
- Trial communities are familiar discussing products and delivery methods vs inducing a natural/immune response
- Getting the nomenclature right: Vaccine knowledge = immunisation, or C19 or something else ?
- Transitioning knowledge to a wide range of unfamiliar scientific concepts will require effort



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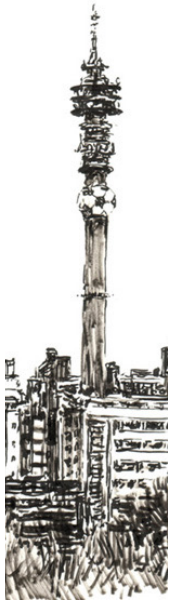

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Our Call to Action: Do GPP best!

Phase 1: GPP Planning must occur 3-6 months before the first px is enrolled

1. **DTS Formative Research** that influences protocol and strategies
2. CAB **advisory**
3. Investigator/protocol-driven **plans**:
   - Recruitment **&** Retention
   - Community **&** Stakeholder Engagement **&** Education
   - Communication **+** Team
   - Issue Management
   - PTA considerations: **pathways**

Align activities to an iterative design

Phase 2: Monitoring Implementation holds every role-player accountable

4. **Adjust/Align** Protocol
5. Deploy **Informed Consent**
6. **Standard** of Care provision
7. **Support Access** to Care & Treatment for HIV / other harms
8. **Mitigate** Trial-related harms
9. **Implement and Monitor** Phase 1 Plans

Cross-pollinate iterations for efficient engagement from global to site levels

Phase 3: Concluding (a) trial(s) coherently consolidates GPP capability

10. Accrue & **follow-up**
11. Close trial(s) and disseminate results to **participants**
12. Disseminate results to **regulators, scientific community, CAB, Trial Stakeholders, Trial Community**
13. Follow **post-trial access** pathways
14. **Publish** GPP practices and lessons

Build learning through dissemination

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So what? Where do we go from here?

Game-changer: shared understandings with no firm comfort in one outcome

Start with the end in mind - map pathways

Sustained community investments in research literacy and formative research

Accept the timelines will be different from previous game-changers (within reason)

Build value and validity with community partners

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Thank You to all my collaborators!

PEPFAR

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