EATG PROMise Project

Recommendation Consultations Report

Kevin Moody

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PROMise

Acknowledgements

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Author
Kevin Moody

EATG PROMise Task group
Raminta Stuikyte
Alain Volny-Anne
Brian West

Academic Advisors
Diana Barger, University of Bordeaux
Caroline Sabin, University College London

Academic Clinicians
Marc van der Valk, Amsterdam UMC
Giovanni Guaraldi, University of Modena and Reggio Emilia

Pharmaceutical Industry
Felipe Rogatto, Gilead Sciences
Sophie Noya, Merck Sharp & Dohme
Lital Young, Merck Sharp & Dohme
Christina Donatti, ViiV Healthcare
Tokunbo Soyemi, Gilead Sciences
Nneka Nwokolo, ViiV Healthcare

EATG Secretariat and Members
Giorgio Barbareschi
Fiona Greenhalgh
Rocco Pignata
Christos Krasidis

Design
Sophie Monk
Apostolos Kalogiannis

Contents

Introduction

EATG convened a stakeholder workshop on patient-reported outcome measures (PROMs) in HIV Research and Development in Brussels, Belgium on June 17, 2022. The workshop arose from a consultation process with stakeholders that reviewed recommendations from the research paper, PROMs in HIV Research and Development: Analysis of Community Needs and Engagement. After a workshop held during the European AIDS Conference in London in October 2021, and subsequent focus group discussions with community, academia/ clinicians, and pharmaceutical companies, many of the original recommendations in the research paper were endorsed. However, there was unanimous agreement that these needed to be further developed in a face-to-face workshop involving all stakeholders.

Workshop Goals

1 Explore new HIV treatment products in the pipeline and the characteristics that will differentiate them from existing products.

- **a.** Differences in populations and types of products
  - **i.** Therapeutic solutions for people with specific needs such as multi-drug resistant HIV
  - **ii.** New compounds in existing classes
  - **iii.** New administration methods / approaches

2 Define and characterise the different PROMs used in HIV R&D studies.

- **a.** Distinguish between PROMs
  - **i.** Regular standard care
  - **ii.** Differentiate new products from existing ones based on specific product characteristics
  - **iii.** Patient preferences / satisfaction
- **b.** Compare characteristics of ideal endpoints with PROMs in specific settings

3 Discuss possible consensus-building methodologies and agree on next steps to facilitate wider consultation of concepts developed at the workshop.

Agenda

June 17, 2022
Hôtel du Congrès, Brussels

Time	Topic	People
10:00	Welcome and introductions	Pieter Vanholder, Executive Director, EATG
10:10	Background update on EATG's work on PROMs in HIV R&D	Kevin Moody
10:20	Desirable attributes of PROMs to address new products	Caroline Sabin
	What's in the pipeline?	Marc van der Valk
11:20	Coffee Break	
11:35	Regulatory participation	Diana Barger
12:15	Lunch	
13:15	Introduction to Delphi and other consensus-building methodologies	Kevin Moody
13:35	Discussion on feasibility and desirability of adopting a methodology for this work	Kevin Moody
14:15	Agreement on timelines, people to invite to participate, logistics, etc.	Giorgio Barbareschi
14:45	Summary and closure	Pieter Vanholder
15:00	Adjourn	

Summary

Kevin Moody summarised PROMise work completed to date, including the results of the research paper and the consultations that followed, providing the rationale for the stakeholder workshop. This was followed by a joint session by Caroline Sabin and Marc van der Valk, who described (1) the ideal features of PROMs in relation to the ideal features of new products and (2) the product pipeline and thus the types of PROMs that would be useful in HIV R&D trials. This led to a discussion about the different types of PROMs and the requirements of those used for clinical trials versus those used as part of routine clinical care. It was noted that there is a need for guidelines for the use of PROMs in clinical practice and although EACS had agreed to address this issue, they have yet to do so.

Diana Barger facilitated a discussion around the involvement of regulators and health technology assessment agencies (HTAs) in these discussions. To date, regulators have not been involved in the PROMise process. The importance of including HTAs was emphasised, even more so than regulators. Colleagues from industry stressed that PROMs should be included to not only help to differentiate between existing and new drugs/health technologies but also to ensure that these are adopted by national health systems and providers. The value of PROMs for all stakeholders, including patients who might benefit from comparative PROMs data, available to them at point of care, was also highlighted. There was consensus among stakeholders that regulators and HTAs be involved to better inform discussions around the use of PROMs in HIV R&D. Thereafter, Kevin Moody presented the Delphi process as a possible way to move towards consensus among stakeholders. Most participants had not been part of such a process, although two had been. Examples of Delphi processes used successfully in HIV illustrated that this could be viable for the work that the PROMise project aims to achieve.

The discussion of consensus evolved into a debate around the use of PROMs in clinical trials versus routine clinical care. Some stakeholders thought that the same instruments could, and even should, be used for both, while others argued that the requirements of PROMS for use in HIV R&D trials were different, as the PROMs needed to be able to differentiate new products. This debate echoed discussions in the stakeholder focus groups that took place virtually. There was no consensus on how product-differentiating should be developed and used in HIV R&D trials.

It was noted that there were still no universally accepted PROMs for HIV drug trials (unlike oncology). It was suggested to partner with organisations/working groups that seek to develop standardised measures for each disease area. In addition to PROMs that differentiate based on specific product characteristics, future HIV medicines development should prioritise additional endpoints beyond viral suppression to include health-related quality of life (HRQoL) or its specific domains. The choice of PROMs which evaluate said domains

should be valid, reliable, and sufficiently responsive to change to capture potentially minor differences between experimental and existing products. Narrowing down the list of "fit for purpose" PROMs should be prioritised in future work.

Next Steps

1 Delphi Process: Desirable PROMs domains for HIV R&D

- Develop a list of domains for PROMs in HIV R&D that are of value to people with HIV and/or address unmet needs, including areas where HRQoL could be improved.
- Conduct Delphi process.

2 Overview GRID of HIV medicines pipeline

- Describe the types of products that are likely and desirable medicines for HIV.
- Given the time required to develop PROMs, include product types that are likely to evolve in the next 5 to 10 years.
- Focus on patient characteristics, type of drug, route of administration, types of drug trials, etc.

3 Mapping exercise

- Consult databases to identify PROMs instruments that exist and are used in HIV R&D, and map these to the domains identified in the Delphi process.

4 Meet to discuss results and next steps

- Convene in Amsterdam when results from the first three activities are completed.
- Ensure that representatives from EMA participate in the meeting (hence, the Amsterdam location).
- Ensure that representatives from HTAs participate in the meeting.
- Plan for the journal supplement and other next steps, such as joint communications, etc.

5 Publish results in journal supplement

- Work with a renowned journal to publish a supplement that includes the results of the PROMise programme, including the research paper, consultation reports, and results from the three above follow-up activities from this workshop.

List of Participants

Name	Affiliation	Stakeholder
Caroline Sabin	University College London	Academia
Diana Barger	University of Bordeaux	Academia
Giovanni Guaraldi	University of Modena and Reggio Emilia	Academia/Clinician
Marc van der Valk	Amsterdam UMC	Academia/Clinician
Sophie Noya	Merck Sharp & Dohme	Pharma
Lital Young	Merck Sharp & Dohme	Pharma
Christina Donatti	ViiV Healthcare	Pharma
Tokunbo Soyemi	Gilead Sciences	Pharma
Nneka Nwokolo	ViiV Healthcare	Pharma
Felipe Rogatto	Gilead Sciences	Pharma
Maryan Said	EATG, Norway	Community
Alain Volny Anne	EATG, France	Community
Brian West	EATG, Scotland	Community

Name	Affiliation	Stakeholder
Kevin Moody	EATG (Research consultant)	Community/ Academia
Christos Krasidis	EATG (Comms and training consultant)	Community
Giorgio Barbareschi	EATG Staff (Partners in Science Programme Manager)	Community
Rocco Pignata	EATG Staff (Project and Admin Intern)	Community
Fiona Greenhalgh	EATG Staff (Partners in Science Project Officer)	Community
Pieter Vanholder	EATG Staff (Executive Director)	Community
Anton Basenko	EATG Staff (Quality of Life Programme Manager)	Community
Adama Thorlie	EATG Staff (Quality of Life Project Officer)	Community


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