

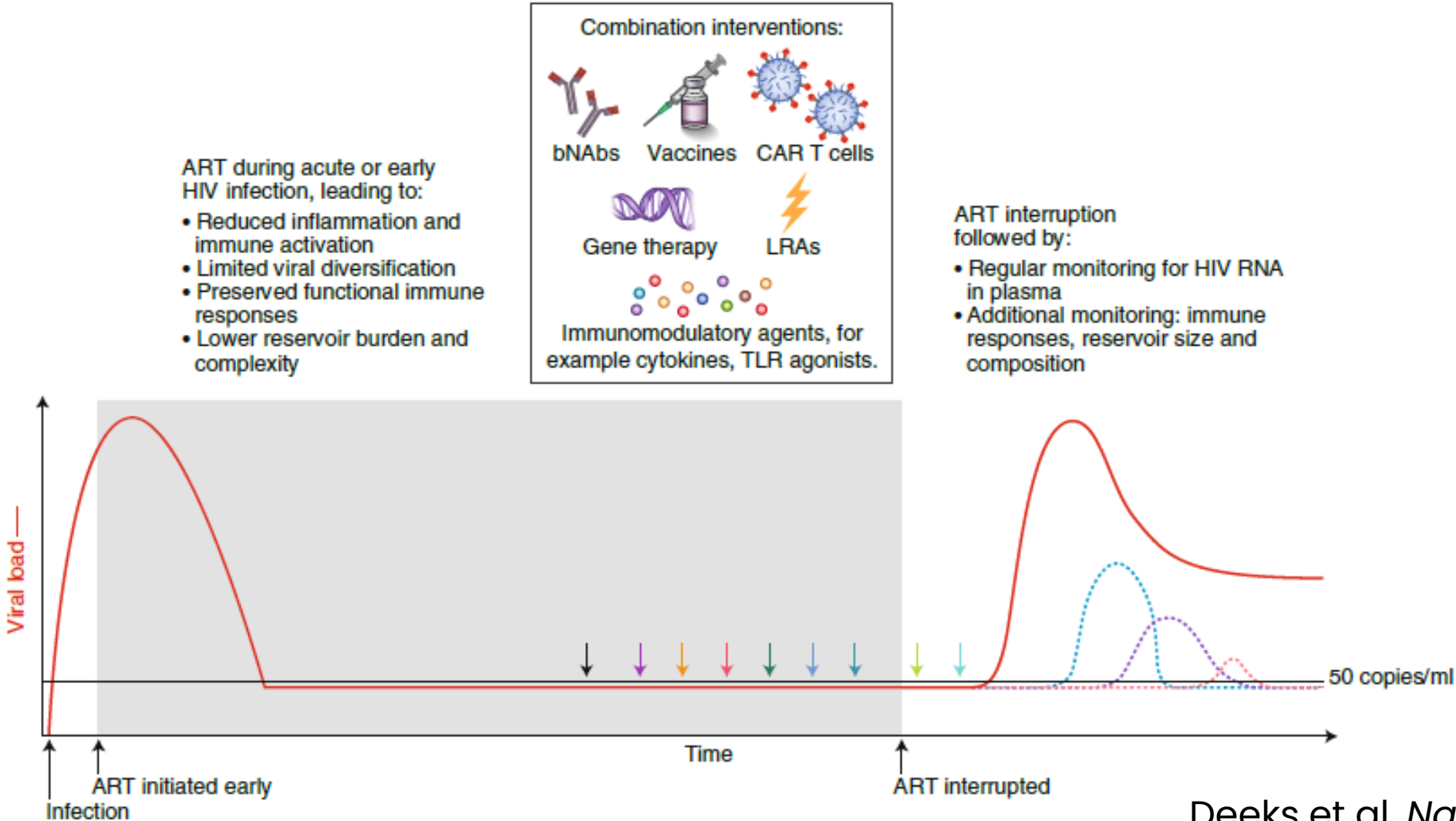


# Key Messages from the 2<sup>nd</sup> Consensus Workshop on Analytical Treatment Interruption (ATI) in HIV Cure Trials

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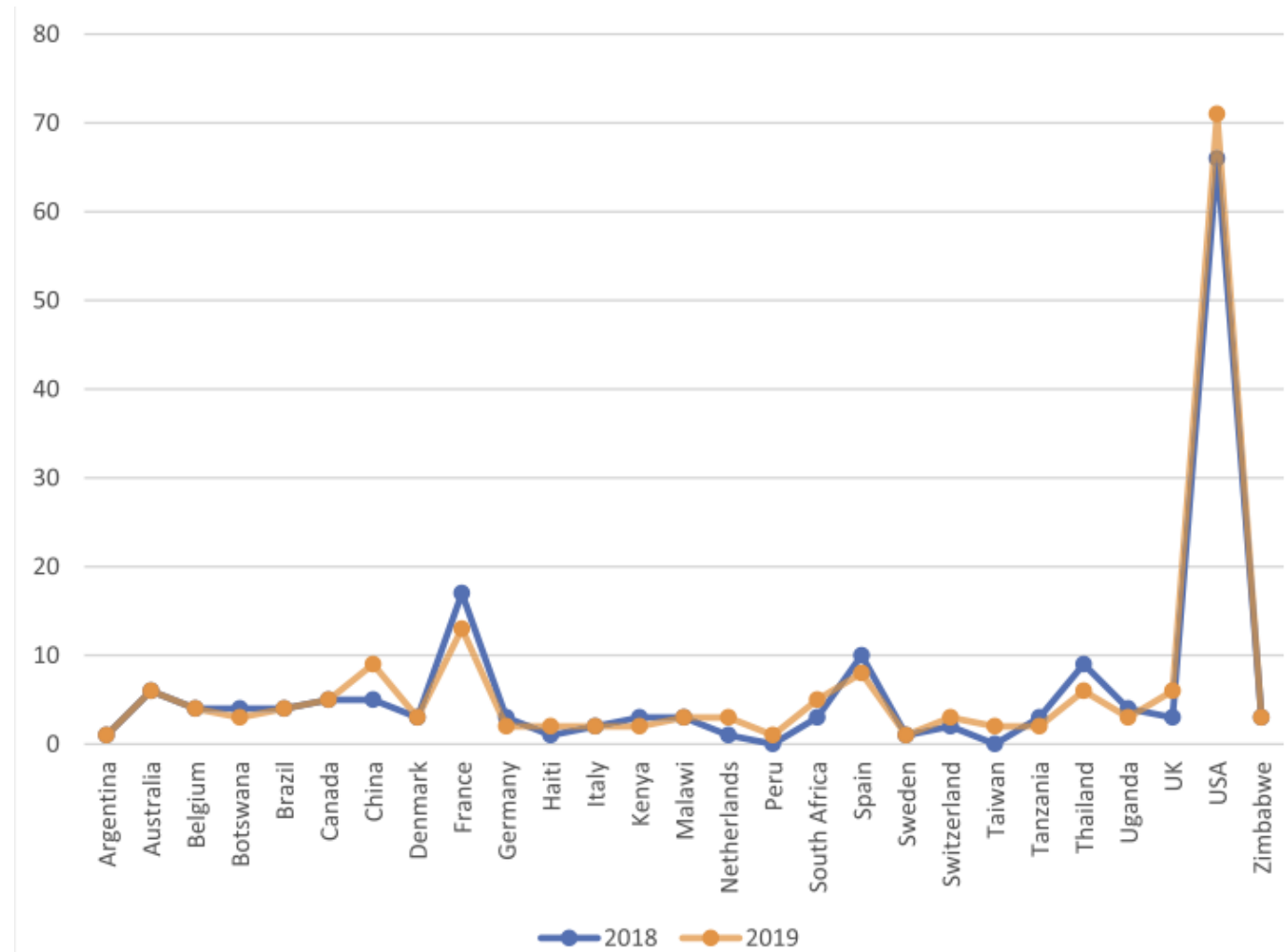
# The IAS scientific strategy recognizes the importance of ATIs for accelerated progress in HIV cure research



# HIV cure research landscape

- Cure research predominantly done in low HIV prevalence settings
- Academic settings, well resourced institutions in Global North
- Paucity of research in Global South
  - Lack of local expertise?
  - Lack of infrastructure?
  - Lack of regulatory systems?
  - Lack of political will?
  - Lack of advocacy?

Geographic Distribution of Cure Studies 2018–2019



# Time to rebound versus set point ATI

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	<b>Time to rebound ATI</b>	<b>Set point ATI</b>
<b>Design</b>	Resume ART immediately once viral load detectable	Resume ART if an agreed set point is not achieved

# Building on previous work

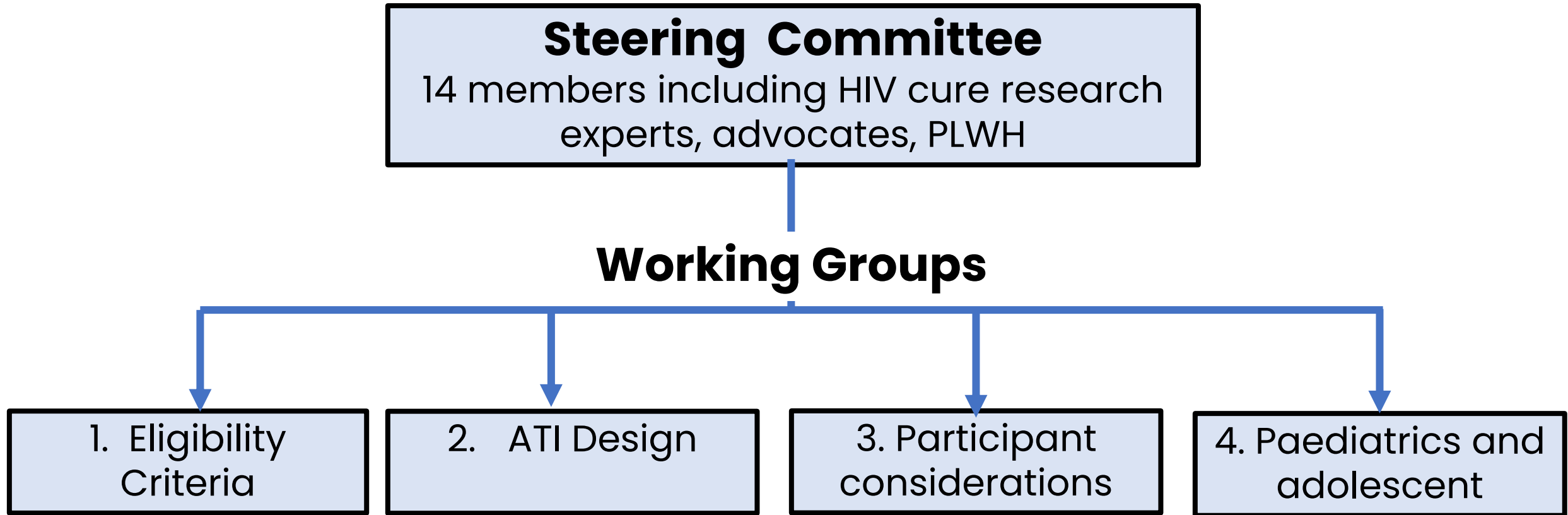


## Recommendations for analytical antiretroviral treatment interruptions in HIV research trials—report of a consensus meeting

*Boris Julg, Lynda Dee, Jintanat Ananworanich, Dan H Barouch, Katharine Bar, Marina Caskey, Donn J Colby, Liza Dawson, Krista L Dong, Karine Dubé, Joseph Eron, John Frater, Rajesh T Gandhi, Romas Geleziunas, Philip Goulder, George J Hanna, Richard Jefferys, Rowena Johnston, Daniel Kuritzkes, Jonathan Z Li, Udom Likhitwonnawut, Jan van Lunzen, Javier Martinez-Picado, Veronica Miller, Luis J Montaner, Douglas F Nixon, David Palm, Giuseppe Pantaleo, Holly Peay, Deborah Persaud, Jessica Salzwedel, Karl Salzwedel, Timothy Schacker, Virginia Sheikh, Ole S. Søgaard, Serena Spudich, Kathryn Stephenson, Jeremy Sugarman, Jeff Taylor, Pablo Tebas, Caroline T Tiemessen, Randall Tressler, Carol D Weiss, Lu Zheng, Merlin L Robb, Nelson L Michael, John W Mellors, Steven G Deeks, Bruce D Walker*

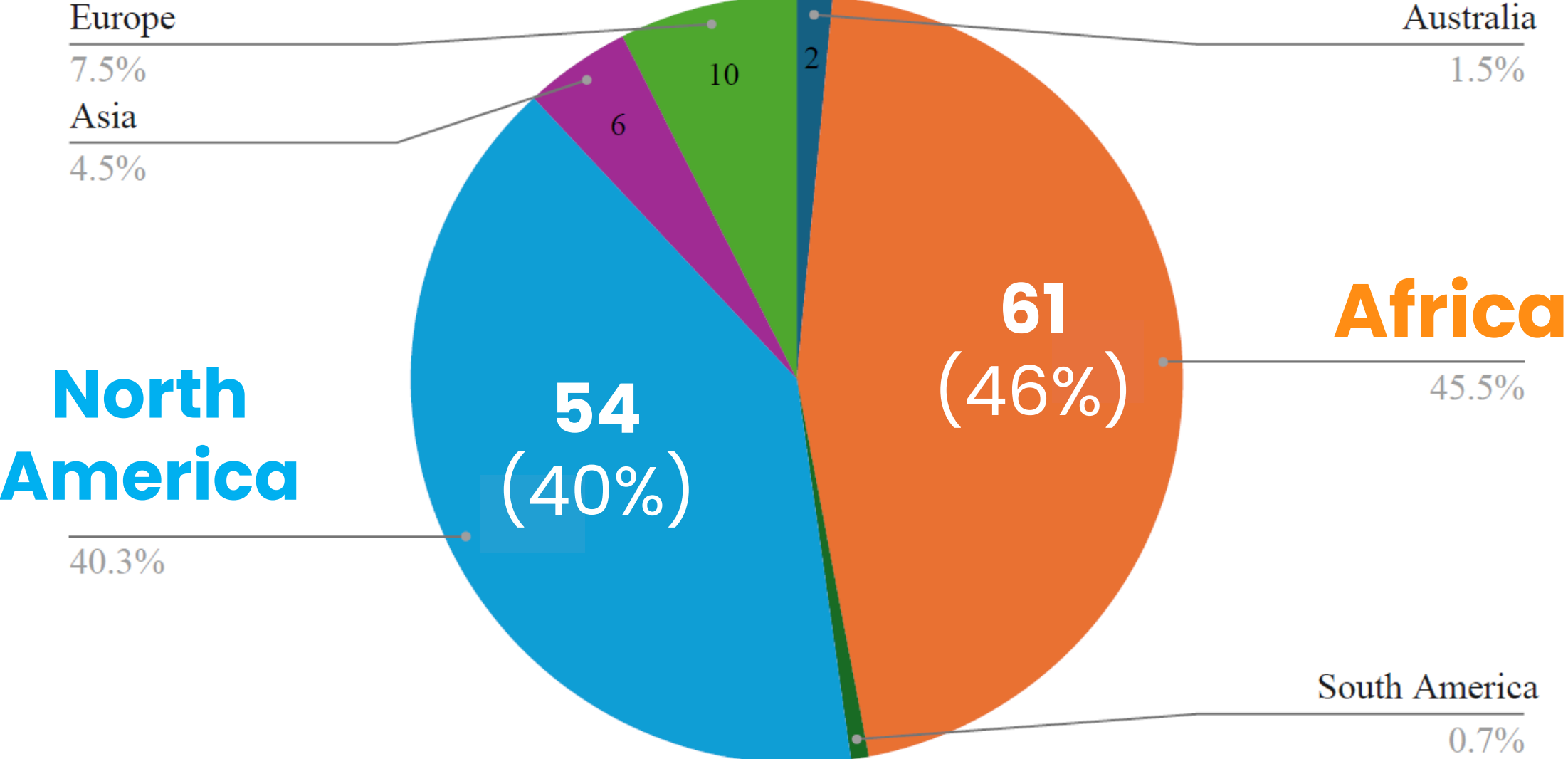
- A lot has been learnt since the previous workshop
- Need to more participants with experience and perspectives from LMICs
- Paediatrics and adolescent populations

# Planning for the 2024 ATI Consensus Workshop



Working groups met regularly to gather evidence and consult beyond the Steering Committee, and to formulate a list of key issues for consensus voting

# Demographics by region (N=134 attendees)



# Overview of 2024 ATI Recommendations (draft)

	2019	2024	Comments
ELIGIBILITY	<ul style="list-style-type: none"> <li>Stable CD4 &gt;500; CD4 nadir &gt;200,</li> <li>exclude VL blips and cardiovascular risk</li> </ul>	Include all CD4 despite nadir CD4 counts, allow VL blips if not within the past year, exclude active CVD, not risk	More relaxed CD4 criteria, allow VL blips prior to ATI and allow participants with previous but no current comorbidities
ATI DESIGN	<ul style="list-style-type: none"> <li>VL monitoring weekly for 12w, then every 2w.</li> <li>ART restart criteria               <ul style="list-style-type: none"> <li>VL <math>\geq</math>1,000 x 4w</li> <li>VL <math>\geq</math> 100,000 confirmed</li> <li>CD4 <math>\leq</math>350</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>VL monitoring every 2w</li> <li>ART restart criteria               <ul style="list-style-type: none"> <li>VL &gt;1,000 for X wks (cont if declining)</li> <li>VL &gt;100,000 confirmed, restart ART</li> </ul> </li> </ul>	Continue to monitor post-ATI for long-term AE associated with of ATI, impact on reservoir
PARTICIPANT CONSIDERATIONS	<ul style="list-style-type: none"> <li><b>Referral</b> for PrEP and HIV testing of partners</li> <li><b>Recommended</b> psychosocial monitoring</li> </ul>	<ul style="list-style-type: none"> <li><b>Provide PrEP</b> or established reliable referral site(s)</li> <li><b>Provide</b> psychosocial support</li> </ul>	Improved participant protection measures, including mental health & strategies to reduce transmission during ATI
PAEDIATRICALS and ADOLESCENTS	Not included in previous guidelines but age <2 years was an exclusion criteria	Monitoring for acute retroviral syndrome, stringent CD4 criteria; exclude <2 years	Improved measures for psychosocial support, clinical monitoring, age restrictions



# Acknowledgements



## STEERING COMMITTEE

- Krista Dong
- Lydie Trautmann
- Victoria Kasprowicz
- Moses Supercharger Nsubuga
- Steven Deeks
- Boris Juelg
- Mark Cotton
- Philip Goulder
- Donn Colby
- Trevor Crowell
- Karine Dube
- Randall Tressler
- Sharon Lewin
- Thumbi Ndung'u

