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Global Accelerator for Paediatric formulations
WHO Hosted Network

World Health Organization

Paediatric drug optimization for respiratory syncytial virus

Meeting report, April 2025

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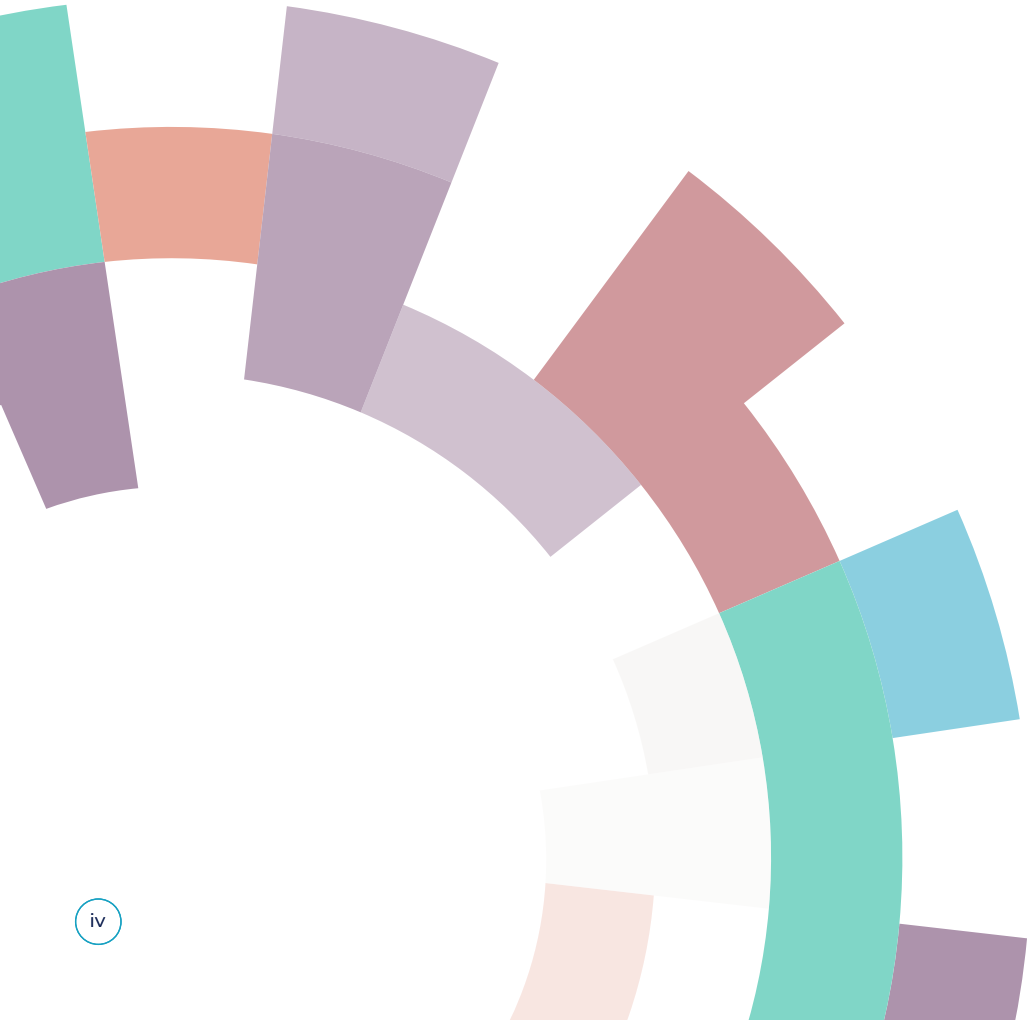


The need for paediatric drug optimization

The development of medicines for children lags unacceptably behind that for adults by nearly a decade.

Following the resolution at the Sixty-ninth World Health Assembly on promoting innovation and access to quality, safe, efficacious and affordable medicines for children *(1)*, WHO and partners have increased their efforts to deliver on this global commitment and have scaled up activities to ensure that age-appropriate formulations are available for children. The Global Accelerator for Paediatric Formulations Network (GAP-f), a WHO-hosted network, works across the life cycle of drug development to accelerate the investigation, development and introduction of optimal formulations for children *(2)*. Priority-setting is the first step to enable a targeted approach to research and development. Developing a priority drug portfolio of the most needed formulations for children is essential to streamline researchers' and supplier's efforts and resources around specific dosage forms and formulations that address the most urgent needs for children.

This is especially important since the market for medicines for children is often small and/or fragmented, resulting in limited volumes with potential market failures. Paediatric drug optimization (PADO) exercises to identify key priority products and their preferred product characteristics for research and development have been successfully undertaken for human immunodeficiency virus (HIV), hepatitis C, tuberculosis, coronavirus disease 2019 (COVID-19), antibiotics, neglected tropical diseases and childhood cancer, demonstrating their potential and impact to accelerate access to optimal formulations in the context of fragmented, small markets for medicines for children. To provide further guidance to support similar processes for optimizing drugs for children in other disease areas, GAP-f has published a guidance document to undertake a PADO process and adapt it to the specific needs of each disease area *(3)*.

PADO for respiratory syncytial virus

Respiratory syncytial virus (RSV) is one of the leading causes of lower respiratory tract infections (LTRI), hospitalizations and mortality among young children globally.

RSV is estimated to cause 101 400 deaths, 3.6 million hospitalizations and 33 million RSV-LRTI episodes among children younger than five years of age annually. About 97% of all RSV deaths occur in low- and middle-income countries (LMICs), where many deaths occur before presentation to a health facility. Nearly half the RSV deaths occur among infants younger than six months *(4)*. RSV occurs in seasonal epidemics in temperate settings, circulates year-round with seasonal peaks in semi-temperate settings and can cause year-round disease in equatorial regions. The timing of RSV circulation can vary year to year, adding complexity to prevention efforts *(5)*. The duration of protection given by prevention measures becomes thus very important.

Supportive care, including possible hospitalization based on severity, is the main strategy for managing most children with RSV. There is no specific treatment for RSV, highlighting the importance of preventive measures. Moreover, studies suggest that RSV causes substantial volumes of antimicrobial prescribing among young infants, which affects microbe composition and contributes to the emergence of antimicrobial resistance *(6, 7)*.

Three products, nirsevimab, clesrovimab[1] and an RSV prefusion-F protein vaccine (RSVPreF), have recently been licensed for preventing severe RSV disease among infants.

Nirsevimab is a long-acting, recombinant monoclonal antibody that targets the RSV prefusion-F protein, and clinical trials have demonstrated its safety and efficacy for infants *(8)*. It was first licensed in Europe at the end of 2022 and has demonstrated high effectiveness in initial post-marketing studies in several high-income countries *(9)*. It is given as a single intramuscular injection to babies shortly before the RSV season at a dose of 50 mg for infants weighing less than 5 kg and 100 mg for those weighing 5 kg or more. In addition to healthy infants, RSV antibody can be administered to high-risk children 8–19 months old with conditions such as prematurity, chronic lung disease, immunocompromised status or severe cystic fibrosis. RSV antibodies provide protection against RSV disease for at least five months.

RSVPreF is a bivalent prefusion-F protein vaccine licensed in 2023, is administered as a single intramuscular injection to pregnant individuals in late pregnancy to protect their infants through the transplacental transfer of antibodies. In a Phase III clinical trial, which enrolled pregnant people between 24–36 weeks of gestation, efficacy was high against RSV-positive severe medically attended LRTI (vaccine efficacy = 70%; 95% CI: 51–83) and RSV-positive medically attended LTRI (vaccine efficacy = 49%; 95% CI: 31–63) in infants up to 180 days after birth. The efficacy was similar across countries of varying income levels.

1 Clesrovimab was pending market authorization at the time of the meeting.

Both nirsevimab and the RSVPreF vaccine have received market authorization in more than 60 countries. The manufacturer of the RSVPreF vaccine has made a global access commitment to develop a multidose vial presentation and supply the vaccine at an affordable price to LMICs through public sector purchases, including through Gavi. Currently, there is no such price commitment enabling LMICs to access nirsevimab. On top of a price issue, the nirsevimab product presentation is not optimized for use in LMICs, since the product comes in prefilled syringes that do not have an autodisable needle, requiring a lot of cold-chain space and carrying the risk of syringe reuse.

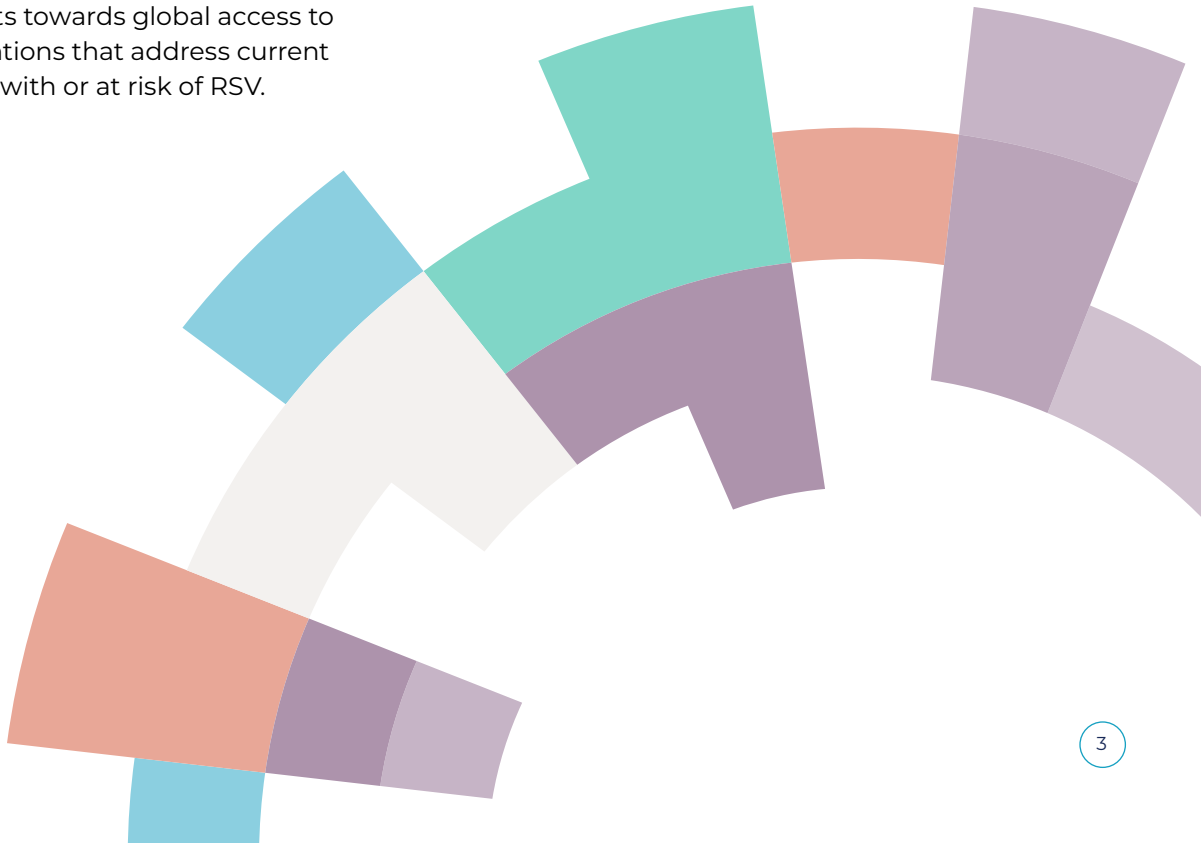
Given the global burden of RSV disease, in 2024 the Strategic Advisory Group of Experts on Immunization and WHO recommended that all countries introduce products for preventing severe RSV disease among infants *(10)*. Decisions to use maternal vaccination and/or nirsevimab should consider cost, financing, supply, anticipated coverage and feasibility of implementation within the existing health system.

A formal WHO position paper outlining WHO's policy recommendations and considerations for countries to introduce either of both products has been published *(11)*.

The PADO-RSV exercise was designed with the overall goal of better targeting research and development efforts and promoting the alignment of efforts towards global access to paediatric interventions that address current needs for children with or at risk of RSV.

About 97%

of all RSV deaths occur in low- and middle-income countries



Objectives

PADO-RSV focused on both prevention and treatment of RSV disease, addressing long-acting monoclonal antibodies and antiviral agents in the context of an evolving landscape in which the maternal RSVPreF vaccine is being implemented, and a paediatric vaccine is being investigated.

The specific objectives of PADO-RSV included:

- to review and set priorities for tools for RSV prevention with a focus on monoclonal antibodies considering:
  - available products and pipeline products;
  - the need to promote global access; and
  - the broader context in which other interventions are available or being investigated (maternal vaccine and paediatric vaccine);
- to review and set priorities for antiviral agents that are currently marketed or being investigated for the treatment of RSV disease, considering the development timeline, preliminary efficacy and safety results, route of administration and mechanism of action; and
- to discuss priority research questions and access considerations to foster alignment and targeted efforts.

Overall, the goal of the PADO-RSV exercise was to develop a PADO priority list of therapeutics for which priorities will be set with a time horizon of 3–5 years and a PADO watch list containing promising candidates for investigation and development for children with a time horizon of 5–10 years.

The PADO–RSV exercise enables alignment between funders, procurers, market coordination entities, researchers, innovators, generics manufacturers, product development partnerships and regulators on priority products to be investigated and developed and increasing efforts to tackle challenges in access to available and upcoming interventions for RSV in LMICs.

Methods

The available resources published by WHO for RSV were reviewed, including recommendations by the Strategic Advisory Group of Experts on Immunization *(10)*, the WHO global market study on RSV immunization products *(12)* and the WHO preferred product characteristics of monoclonal antibodies for passive immunization against RSV disease *(13)*.

The priority-setting exercise focused on long-acting monoclonal antibodies and antiviral agents and was undertaken separately for the two categories of interventions.

For long-acting monoclonal antibodies, an existing monoclonal antibody technology landscape and an RSV clinical trial tracker were used as reference documents *(14, 15)* and complemented by information available in peer-reviewed publications and collected directly through bilateral engagement with relevant companies. Long-acting monoclonals considered for priority-setting included products marketed at the time of the meeting (nirsevimab) and those in late-stage clinical development (clesrovimab, TNM001).

For antiviral agents, clinical trial data were obtained from two complementary sources available in the WHO Global Observatory on Health Research and Development: the WHO International Clinical Trials Registry Platform *(16)* and AdisInsight *(17)*, a commercial database that provides structured information on drug development programmes, including product-level details and associated clinical trials. Both datasets were filtered to retain entries relevant to RSV. For the WHO International Clinical Trials Registry Platform data, only interventional trials were retained, and disease-relevant keyword filters were applied. The final integrated datasets, cleaned and standardized using in-house scripts, was the basis for downstream analysis of the RSV drug development landscape.

The analysis focused on compounds in Phase II or III clinical development. The results of this analysis were then further screened and validated with information from peer-reviewed publications and other publicly available information to assess which compounds were still in active development or had been discontinued.

Before the meeting, two dedicated priority-setting frameworks were developed (Table 1) and populated with information collected from relevant WHO documents, scientific publications, clinical trial databases and ad hoc outreach to relevant developers. Of note, the priority-setting framework for monoclonal antibodies was developed based on the WHO preferred product characteristics of monoclonal antibodies published in 2021 *(13)*, which considered the specific characteristics and needs that might be unique to LMICs.

Table 1. Attributes included in the priority-setting frameworks of PADO for RSV for long-acting monoclonal antibodies and antiviral agents

Monoclonal antibodies	Antiviral agents
Mechanism of action	Mechanism of action
Phase of development	Phase of development
Route of administration	Route of administration
Product presentation	Molecule class (new or repurposed)
Indication	Already used for children with another indication
Target population	Primary endpoints of studies completed or ongoing
Dosing schedule	Efficacy
Efficacy	Safety
Safety	Tolerability profile and use for those with organ impairment
Strain specificity	Side-effects
Considerations on co-administration with other interventions	Preclinical signals
Registration and programmatic suitability	Known drug–drug interactions
Access and affordability	Activity against difficult-to-treat resistance profiles
	Resistance potential
	Laboratory and clinical monitoring
	Screening required before administration
	Paediatric formulation
	Storage requirements
	Regulatory considerations

Meeting proceedings

The PADO for RSV meeting was held virtually on 8 and 10 April (Annex 1) and brought together academics, researchers, clinical experts, regulators, funders and other key stakeholders involved in research and development related to RSV (Annex 2). Conflict-of-interest declarations were collected for all participants and closely reviewed. Nine participants with relevant conflicts were asked to participate as observers and withdrawn from the priority-setting process, given their involvement in activities related to the development, implementation and regulatory approval of specific monoclonal antibodies.

Consensus on priority monoclonal antibodies and antiviral agents to be further investigated and/or developed for infants and children was reached through working group discussions informed by the prepopulated frameworks described above. The final PADO priority and watch lists for RSV and corresponding research agendas were developed during a final plenary session.

Summary of discussions

Long-acting monoclonal antibodies for preventing RSV disease

The PADO for RSV group reviewed and discussed monoclonal antibodies that have been licensed for preventing RSV disease (nirsevimab and clesrovimab[2]) and that are in late-stage clinical development (TNM001) (Table 2).

The PADO for RSV group's discussions focused on aspects including the results of clinical trials, the suitability of the approved or expected product presentation and dose and considerations for global access plans. Discussions considered the broader context of other available interventions or interventions under development, notably the maternal and paediatric vaccine.

[2] Clesrovimab was pending market authorization at the time of the meeting.

Table 2. Summary of characteristics of long-acting monoclonal antibodies that were approved and are under clinical investigation.[a,b]

	Nirsevimab	Clesrovimab	TNM001
Phase of development	Approved by the European Medicines Agency (November 2022) and by the United States Food and Drug Administration (July 2023)	Approved by the United States Food and Drug Administration (June 2025)	Phase IIb/III ongoing (China), expected completion in 2026 (Prequalification by WHO would require stringent regulatory authority approval)[c]
Administration	Single intramuscular injection	Single intramuscular injection	Single intramuscular injection
Product presentation	Prefilled syringe without autodisable needle and temperature monitor (for supply chain)	Prefilled syringe without autodisable needle and temperature monitor (for supply chain)	Single dose vial (no temperature monitor for supply chain for the moment)
Volume	50 mg/0.5 mL 100 mg/1.0 mL	105 mg/0.7 mL	120 mg/1.2 mL
Dose	<5kg: 50 mg ≥5kg: 100 mg	105 mg regardless of weight and whether they are born during the RSV season or outside it	120 mg regardless of weight
Programmatically suitable presentation for LMICs	Not yet available	Not yet available	Not yet available
Access and affordability for LMICs	Not yet met	Not yet met	Not yet met

[a] The characteristics listed and assessed are in accordance with the parameters in the WHO preferred product characteristics of monoclonal antibodies for RSV disease *(13)*. Preferred product characteristics present preferred, rather than required, characteristics of products. Whether or not a product meets the preferred product characteristics criteria, a product can still be assessed for policy recommendations by the WHO Strategic Advisory Group of Experts on Immunization and for WHO prequalification, which assesses product quality, safety, efficacy and suitability for use in LMICs according to the requirements of WHO prequalification expression of interest list (a WHO prequalification expression of interest for monoclonal antibodies for RSV is forthcoming) *(18)*.

[b] The table does not include palivizumab or monoclonals that are being investigated in earlier clinical phases (Phase I). The Gates Medical Research Institute candidate RSM01 was not discussed in the priority-setting framework since its development by the Gates Medical Research Institute has been put on hold after completion of Phase I studies pending the identification of a commercial partner to advance product development further.

[c] From a WHO prequalification standpoint, monoclonal antibodies are considered medicines (not vaccines).

Nirsevimab, which was first approved by the European Medicines Agency in 2022, is now approved in more than 50 countries. However, among those, only eight are LMICs: Argentina, Brazil, China, India, Malaysia, Paraguay, Thailand and Türkiye. Clesrovimab completed Phase IIb/III studies, which showed a 60% reduction in RSV-associated medically attended LRTI, with RSV-associated hospitalizations reduced by 84% and adverse events comparable to the placebo groups, with no treatment-related deaths reported *(19)*. A Phase III trial involving high-risk infants and children such as preterm infants with chronic comorbidities was recently completed, and dossiers were submitted for regulatory approval to the European Medicines Agency and United States Food and Drug Administration. In June 2025, the United States Food and Drug Administration approved clesrovimab. Both nirsevimab and clesrovimab exceeded the 70% efficacy threshold against RSV-confirmed severe disease for five months following administration, as indicated in the WHO preferred product characteristics. TNM-001 is being investigated in a Phase IIb/III trial in China, with expected completion in 2026.

The three products target different binding sites of the RSV prefusion-F protein. All the sites they target are conserved, so they may not have a high potential for escape mutations to occur. The PADO for RSV group reflected on the fact that clesrovimab has a shorter half-life, and even though this does not have any implications for clinical efficacy, the question remains on the duration of protection.

All products meet the strong preference for a one-dose regimen indicated in the WHO preferred product characteristics, but nirsevimab is administered at a different dose depending on the weight of the child (<5 kg, 50 mg; ≥5 kg, 100 mg), which may add programmatic complexity in LMICs. This was not noted to be a programmatic issue in one of the countries (Chile) where the product has been implemented. Clesrovimab and TNM001 have a fixed dose regardless of the weight of the child. The route of administration is via intramuscular injection. The volumes of the prefilled syringes of both nirsevimab and clesrovimab meet the WHO preferred product characteristics target of 0.5 to maximum 1 mL, and the volume of the current presentation of TNM001 that is being studied is 1.2 mL (120 mg/1.2 mL). Both nirsevimab and clesrovimab are supplied in prefilled syringes without an autodisable needle or a temperature monitor on the syringe. The cold-chain requirements for the three products are the same and similar to the standard requirements for vaccines.

The PADO for RSV group agreed that, considering the current features of the products as described above, neither nirsevimab nor clesrovimab meet the WHO targets for programmatic suitability, which should be the same as for vaccines.

The WHO preferred product characteristics indicate that RSV monoclonal antibodies should be accessible and affordable to LMICs to enable broad protection of the most vulnerable infants *(10)*. However, supply capacity is currently limited and there is no commitment to enabling broad access in LMICs, where the burden is highest *(20)*. Moreover, nirsevimab remains unaffordable in most LMICs, at the current price per dose charged in high-income and upper-middle-income countries ranging from US$ 231 to US$ 730. Studies conducted in Kenya and South Africa indicated that a lower price is needed to achieve cost–effectiveness *(21, 22)*. Such a high price also precludes funding by Gavi for purchasing the product, since the price is much higher than the maternal vaccines currently supported.

In conclusion:

The PADO for RSV group agreed that nirsevimab and clesrovimab are expected to be comparable in efficacy and safety, with high strain specificity (both binding sites being highly conserved, with greater than 99% identity across RSV A and RSV B sequences). The PADO for RSV group, therefore, agreed to add both products to the PADO priority list. However, the PADO for RSV group observed that the product presentation of both nirsevimab and clesrovimab does not currently meet the WHO preferred product characteristics. Desirable changes to improve programmatic suitability and global access (such as allowing funding and procurement through Gavi and the United Nations Children's Fund (UNICEF)) include the addition of an autodisable feature for the prefilled syringe or a vial presentation to be administered with an autodisable syringe and a temperature monitor on each prefilled syringe or vial.

Moreover, the volume of clesrovimab is 0.7 mL, which differs from typical vaccine dose volumes of 0.5 mL most commonly used in immunization programmes. Although doses up to 1.0 mL are acceptable for WHO prequalification, most prequalified auto-disable syringes are designed for 0.5 mL. While 1.0 mL autodisable syringes are also prequalified, they are less commonly used, potentially creating supply chain challenges due to the need for larger-volume syringes.

The addition to improved product presentations should be given priority for development. The addition to improved product presentation of both products to the PADO priority list constitutes a strong signal to potential manufacturers of biosimilars entering the market in the future that the current product presentation of both nirsevimab and clesrovimab does not meet the WHO and UNICEF requirements for immunization products and that different product presentations should be given priority for development.

The PADO for RSV group then reviewed the characteristics of the Phase IIb/III candidate TNM001, which is being investigated in China and discussed whether from a clinical or from a programmatic and access standpoint this candidate has potential added value compared with nirsevimab and clesrovimab and considering the broader context of RSV interventions that are available or expected to become available (maternal and paediatric vaccine). It was noted that TNM001 targets an effective epitope of prefusion-F. However, the mutation that leads to extended half-life is different than for clesrovimab and nirsevimab, and there is uncertainty about the half-life of this antibody.

PADO priority list (long-acting monoclonal antibodies)

Nirsevimab[a]

Clesrovimab[a]

[a]In a prefilled syringe with an autodisable feature or vial presentation plus autodisable syringe, in addition to a temperature monitor, meeting the WHO preferred product characteristics targets for critical programmatic suitability and access.

PADO watch list (long-acting monoclonal antibodies)

TNM001 meeting the WHO preferred product characteristics targets for critical programmatic suitability and access.

The PADO for RSV group agreed to add TNM001 to the PADO watch list, signalling that the results emerging from ongoing and future studies on this product will be closely monitored in the future, since there is currently a lack of publicly available information on its clinical characteristics and efficacy. So far, TNM001 trials have only been conducted in China, but there are plans to explore marketing the products outside China. The PADO for RSV group noted that, assuming that the product is shown to be safe and efficacious in Phase III trials, having a third supplier that would initially target specifically the Chinese market and potentially expanding to broader global access[3] would add significant value. For registration in other countries, trials outside China may be required. Engaging in partnerships to supply through Gavi could further strengthen equitable access, especially for LMICs.

Concerns were raised around the potential need for volumes higher than 1.0 mL which is the maximum volume considered suitable for WHO prequalification in accordance with the WHO preferred product characteristics. Volumes higher than 1.0 mL could be an issue,

[3] From a WHO prequalification standpoint, monoclonal antibodies are considered medicines (not vaccines) and as such, prequalification by WHO would first require stringent regulatory authority approval.

especially for premature and low-birth-weight infants, causing undesired adverse events and in general reducing acceptability. Therefore, the PADO for RSV group agreed to list TNM001 in the watch list, specifying that the final product should meet WHO preferred product characteristics targets for programmatic and access suitability and for route of administration (including volume for intramuscular injections)

Considerations on access to long-acting monoclonal antibodies for RSV

Based on key findings from the WHO Global Market Study on RSV immunization products, the adoption of RSV products (including vaccines) in LMICs is expected to evolve at a much slower pace, with introductions several years later than in high-income countries. This is in accordance with other immunization products. The PADO for RSV group highlighted challenges related to access to long-acting RSV monoclonal antibodies in accordance with the WHO Strategic Advisory Group of Experts on Immunization, which "noted with concern the limited availability and high cost of the monoclonal antibody, which will seriously limit global access and equity" *(10)*.

Indeed, for nirsevimab, supply capacity is currently limited and there is no commitment to enabling broad access in LMICs, where the burden is highest. Also, the current price per dose charged in high-income countries and upper-middle-income countries ranges from US$ 231–730, which is prohibitive for LMICs and notably, the cost is the same for a 50 mg and a 100 mg dose *(11)*.

Clesrovimab received market authorization in the United States of America in June 2025. However, no information is available on global access plans.

Patents were granted and filed until 2028–2040 and until 2036 for nirsevimab and clesrovimab, respectively, covering countries with potentially large markets or large manufacturing capacity *(23)*. On the one hand, given the absence of a voluntary licence agreement, independent generic product commercialization of both products can only start in a few years, leading to remarkable delays for affordable access for people in LMICs. On the other hand, although economy of scale may help to bring the price down, broad implementation will not be possible at the currently available prices.

In conclusion:

the PADO for RSV group encourages the originator companies of long-acting monoclonal antibodies that are already marketed to promptly engage with public health organizations to define solid, broad and transparent access plans for LMICs in accordance with the target requirements outlined in the WHO preferred product characteristics for access and affordability. These could include voluntary licensing options to enable more affordable biosimilars monoclonal antibodies to enter LMIC markets while also ensuring enough production capacity and sustainable supply.

These considerations also apply to products that are still being investigated in clinical studies. Since the timeline for end-to-end technology transfer could range from 48 to 60 months (longer than for small molecules), the PADO for RSV group encourages originator companies to engage in these discussions with relevant actors as soon as possible in the development process.

To enhance affordability and equitable access to currently available options until the arrival of biosimilar products, the PADO for RSV group encourages originator companies to develop interim access strategies targeted specifically for LMICs. Promoting wider product registration and considering tiered pricing options for LMICs should be key elements of these strategies. Innovators are encouraged to be mindful of regulatory updates that could accelerate approval pathways for novel long-acting RSV monoclonal antibodies, such as the United States Food and Drug Administration plan to reduce and phase out the need for animal data for new monoclonal antibodies and the European Medicines Agency draft proposal for speeding up biosimilars, based on structural and functional comparability data in tandem with pharmacokinetic data.

The PADO for RSV group also noted that, if a country is only using a birth dose of nirsevimab (50 mg) or only using it for preterm infants weighing less than 5 kg, the production costs for the lower dose are less based on the standard cost of goods per gram of monoclonal antibody. Consequently, if manufacturers base pricing on the production costs per gram, the lower dose has the potential to be priced more affordably than the higher dose.

Finally, the PADO for RSV group reflected on localizing monoclonal antibodies production in LMICs and its potential to reduce manufacturing and distribution costs by shortening supply chains, reducing import dependence and enabling region-specific formulation. Several African manufacturers have expressed strong interest in producing affordable monoclonal antibodies for infectious diseases such as RSV, which opens new pathways to broaden access and ensure availability where it is needed most.

Antiviral agents for the treatment of RSV disease

Aerosolized ribavirin is the only therapy approved for the treatment of RSV disease, and it is used only in very limited situations, given concerns about low efficacy and an unfavourable safety profile, thus signalling an urgent need for safe and effective therapeutics to be developed.

The PADO for RSV group reviewed and discussed antiviral agents that are currently being investigated for the treatment of RSV disease, focusing on aspects including the results of completed studies, mechanism of action of the candidates under investigation and their route of administration.

The results from a preliminary analysis of the WHO International Clinical Trials Registry Platform and AdisInsight databases were prescreened to focus the priority-setting exercise on active candidates investigated for RSV. Antiviral agents recently discontinued from clinical development were not included in the analysis (Box 1). Following this prescreening, some candidates (human interferon alpha-1b, XW 001 and nitazoxanide) were excluded since they were deemed less relevant for the discussions and/or because no information on the current status of development could be found.

Box 1. Antiviral agents recently discontinued from clinical development

Prescreening of the results from the preliminary analysis of WHO International Clinical Trials Registry Platform and AdisInsight databases identified four antiviral agent candidates for which clinical development for RSV was discontinued in Phase II/III. These included sisunatovir and rilematovir (F-protein inhibitors) and lumicitabine and ASC-10 (RSV RNA polymerase inhibitors). In most cases, discontinuation did not result from safety concerns except for lumicitabine, which was associated with dose-related neutropaenia and failed to demonstrate antiviral activity among hospitalized infants infected with RSV in a Phase IIb study. The PADO for RSV group used this information to further reflect on how to optimize trial design for antiviral agents to minimize the attrition rate in Phases II and III while also ensuring that study endpoints can translate into clinical practice (see research priorities).

Among the eight compounds identified, four of them are novel, oral, direct-acting antiviral agents selectively targeting the F-, N- or L-proteins of both RSV-A and RSV-B (Table 3). Ziresovir is the only antiviral for which Phase III trial results are available *(24, 25)* and marketing approval is currently being sought in China (new drug application to be submitted to the National Medical Products Administration in the third quarter of 2025), with plans to expand outside China in the future. The remaining four compounds include repurposed drugs that were investigated and approved for COVID-19. The most advanced candidates are deuremidevir hydrobromide and obeldesivir, which are currently being studied in Phase II or III trials among hospitalized infants. The molnupiravir Phase II human challenge study among healthy adults did not meet the study primary endpoints *(26)*. Except for remdesivir, which is administered intravenously, they are all oral drugs. Remdesivir is the only drug with known pharmacokinetics and safety among children with COVID-19, including neonates (Table 3).

Table 3. Summary of antiviral agents currently being actively investigated for RSV

	New molecule	Route of administration	Mechanism of action	Completed RSV studies	Ongoing or planned RSV studies
Ziresovir	Yes	Oral	F-protein inhibitor	Phase III	Preregistration
Zelicapavir	Yes	Oral	N-protein inhibitor	Phase IIb among children (RSVPEDs, NCT04816721)	Currently discussing Phase III studies (no plans yet)
EDP 323	Yes	Oral	L-protein Inhibitor	Phase IIa human challenge study	No information on plans for follow-up studies
S-337395	Yes	Oral	L-protein Inhibitor	Phase IIa human challenge study	Initiation of adult Phase IIb planned by the end of 2025
Molnupiravir[a]	No	Oral	Viral RNA polymerase inhibitor	Phase IIa human challenge study	Not applicable (primary endpoints of Phase II human challenge study not met)
Obeldesivir[a]	No	Oral	Viral RNA polymerase inhibitor	Not applicable (only remdesivir preclinical evidence available for RSV (see below); no previous studies on RSV, overall safe in COVID-19 trials, no severe adverse events reported).	Phase II safety and tolerability trial among children from birth to <5 years with RSV infection (NCT06784973, recruiting)

Table 3. Summary of antiviral agents currently being actively investigated for RSV

	New molecule	Route of administration	Mechanism of action	Completed RSV studies	Ongoing or planned RSV studies
Deuremidevir hydrobromide[a]	No	Oral	Viral RNA replicase inhibitor	Not applicable (Phase I to evaluate safety, tolerability and pharmacokinetics of deuremidevir hydrobromide suspension in healthy volunteers)	Phase II to evaluate safety, efficacy, PK and antiviral activity (dose finding) in infants hospitalized with RSV aged 1-24 months in China (NCT06206720, recruiting)
Remdevisir[a]	No	Intravenous	Viral RNA polymerase inhibitor	Not applicable (only preclinical evidence of activity against RSV; no human studies on RSV, overall safe in COVID-19 trials, no severe adverse events reported)	Phase II to start in June 2025 in young infants hospitalized with RSV infection

[a] Antiviral agents investigated and approved for COVID-19.

The PADO for RSV group focused their discussions on ziresovir, which showed efficacy in the treatment of RSV disease versus placebo in hospitalized children younger than two years in a Phase III randomized trial in China *(24)* and was associated with a significant reduction in RSV viral load from baseline to day 5 of treatment compared with placebo in a follow-up study among infants aged six months or younger *(25)*. Additionally, the results showed more rapid clinical improvement in the treatment arm, especially for infants younger than six months, evidenced by an earlier reduction in the numeric Wang severity score and a significant decrease in recurrent wheezing in this group on follow-up.

In the trials, the drug was dosed at 10 mg, 20 mg or 40 mg for children weighing 2.5–5.0 kg, 5.0–10.9 kg and 10.0–20.0 kg, respectively, using enteric coated micropellets enclosed in single capsules. Capsules were opened and the content administered after mixing with solid or liquid media (such as yogurt, applesauce, dextran solution or water).

The PADO for RSV group shared the following reflections:

- Wang bronchiolitis score and viral load were the study endpoints: the former is not validated for RSV and the latter does not present a clear clinical correlation.
- A relatively late recruitment mean at day 4 of symptom onset may have affected the final efficacy results.
- No safety concerns were noted.
- Potential emergence of drug resistance should be considered, but no viral rebound or negative impact on clinical efficacy was observed.
- Study enrolment occurred only in China, with under-representation of females, which may warrant further studies across diverse global populations to ensure the broader applicability of the findings.

Despite the limitations discussed above, which are in accordance with considerations published in the literature *(27)*, the PADO for RSV group agreed to add ziresovir to the PADO priority list given the lack of available options to treat RSV disease in children, signalling the need to promote global access to this antiviral agent in a suitable, affordable age-appropriate formulation for children. In addition, to reduce market fragmentation and increase programmatic flexibility across the age and weight spectrum, the PADO for RSV group decided to give priority only to the 10 mg dosage strength currently under investigation. A higher strength formulation was not deemed necessary at this time, since higher doses can be administered with multiples of the lower-dose formulation. The group also noted that alternative oral solid forms that can be dispersed or dissolved could be considered for development.

Given the concerns about the high level of emerging drug resistance in the treatment arm of the ziresovir trial, the PADO for RSV group agreed that additional antiviral agents for RSV are needed and agreed that the focus should be on drugs that can be administered orally. Even for the compounds that are most advanced in clinical development, available evidence is still limited, with relatively small numbers of participants in completed or ongoing studies. In addition, even though some of these compounds were shown to be safe, the use of viral load reduction as a primary endpoint leaves the question of clinical efficacy unanswered. As a result, the PADO for RSV group decided not to give priority to specific Phase II antiviral agents over others and decided to add to the PADO watch list all oral compounds that are currently being investigated in Phase II or III, signalling the need to continue monitoring these clinical development programmes in the future and until late-phase clinical results are available.

PADO priority list (antiviral agents)	PADO watch list (antiviral agents)
Ziresovir 10 mg (enteric coated pellets in single capsule or alternative oral solid forms that can be dispersed or dissolved)	**All oral antiviral agents currently in clinical development** (zelicapavir, EDP 323, S-337395, obeldesivir and deuremidevir hydrobromide)

Additionally, the PADO for RSV group shared the following key considerations, which should be considered in ongoing and planned studies investigating antiviral agents for the treatment of RSV infection.

A strong preference for developing oral RSV medicines was noted, considering the feasibility to administer them at primary care settings compared with injectables. The PADO for RSV group noted that palatability and low volume requirements are key aspects to consider during formulation development and indicated that dispersible tablets or fast dissolving tablets could be valuable options, with the latter being especially helpful for young infants, given the very low volume requirement (of water or breast-milk) for dispersion. The need to be able to administer such formulations via nasogastric tubes was also noted.

In general, the PADO for RSV group highlighted the need for follow-up discussions focused on defining clear preferred product characteristics for antiviral agents to treat children with RSV to guide ongoing and future research and development efforts.

The PADO for RSV group flagged the high attrition rate of antiviral agents investigated for RSV, in accordance with what is reported by GlobalData, which describes a 47% phase transition success rate indication benchmark for Phase II drugs for RSV infection to progress into Phase III *(28)*. Indeed, results from a preliminary analysis of the WHO International Clinical Trials Registry Platform and AdisInsight databases included four candidates that were then found to be discontinued. Other candidates have also been abandoned in the past because of toxicity (presatovir) or clear lack of efficacy (presatovir) *(27)*.

The need to optimize trial design for antiviral agents so that completed studies can provide meaningful information on clinical benefits was indicated as a clear priority for follow-up (see Box 2).

The PADO for RSV group emphasized the need for innovators of antiviral agents that are being investigated for the treatment of RSV infection, especially innovators investigating new molecular entities, to engage with public health organizations to define solid, broad and transparent access plans for LMICs, which have most of the RSV-related morbidity and mortality burden.

Box 2. Research priorities

Following the priority-setting exercise, the PADO for RSV group shared considerations on some research gaps for prevention and treatment of RSV that should be addressed, including specific ones for long-acting monoclonal antibodies and antiviral agents.

General

- Closely monitor the genetic evolution of RSV for potential emergence of RSV resistance against interventions and the clinical presentation of the virus over time.
- Continue monitoring the epidemiology of the disease to evaluate the impact of RSV on older children. Give priority to the out-of-hospital disease burden in low- and middle-income countries.
- To help countries give priority to RSV prevention, conduct RSV epidemiological studies in low- and middle-income country countries to further add data on the burden of disease.
- Explore molecules that would offer protection against RSV and other viruses such as human metapneumovirus and influenza.
- Evaluate the impact of RSV prevention on non-respiratory outcomes such as antibiotic prescribing.[a]
- Evaluate the potential long-term lung health impact of RSV immunization, including recurrent hospitalizations for respiratory illness, recurrent wheezing of childhood and asthma.[a]
- Conduct modelling to determine ideal timing for starting immunization programmes for seasonal approaches in different settings.[a]

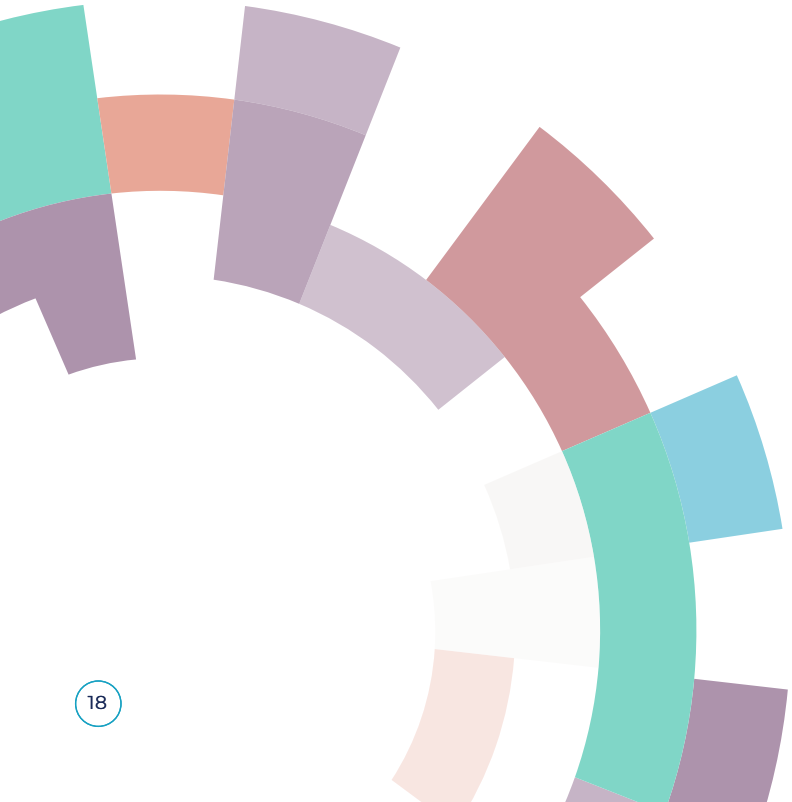
Long-acting monoclonal antibodies for RSV disease for RSV disease

- Conduct long-term molecular surveillance for potential escape mutations in RSV F protein that would allow evasion of immunity and diminish the efficacy of long-acting monoclonal antibody protection.[a]
- Investigate the comparative neutralizing potency and protective thresholds of monoclonal antibody products.
- Investigate across diverse populations the generation of natural immunity among people receiving monoclonal antibodies following subsequent natural exposure.
- Review pharmacokinetic data to evaluate whether lower doses of clesrovimab (currently 105 mg) and TMN001 (currently 120 mg) could be effective to develop more affordable options, especially for smaller infants.
- Investigate the use of long-acting monoclonal antibodies for the treatment of RSV (such as for severe cases), including antiviral monoclonal antibodies to reduce viral load and host-directed immune-modulating monoclonal antibodies that could also play a role in reducing disease, since immune dysregulation contributes to poorer clinical outcomes.
- Study the duration of protection against RSV disease beyond 150 days after administration.[a] This may have important public health implications, especially when seasonality and immunization cannot be precisely estimated.
- Investigate whether administering monoclonal antibodies during the first year or season affects RSV disease during the second year or season.
- Investigate comparative effectiveness between (soon-to-be-) marketed long-acting monoclonal antibodies as they are being introduced (post-market studies) and compare with real-world vaccine effectiveness.
- Conduct implementation research to determine optimal strategies for integrating monoclonal antibody administration into existing health-care programmes, including as part of postpartum preventive care.[a] This would enable its potential integration with RSV maternal immunization programmes to be explored, the acceptability and feasibility of the intervention to be evaluated and the impact measured in terms of burden of mortality and hospitalization.
- Collect more real-world evidence on the use of nirsevimab (and clesrovimab as it is being introduced).
- Carry out cost–effectiveness studies in low- and middle-income countries using local inputs and willingness-to-pay thresholds, including evaluating seasonal approaches in appropriate settings.[a] Country-specific cost–effectiveness studies could support and justify the introduction of monoclonal antibodies versus maternal vaccination in specific contexts.
- Investigate whether RSV long-acting monoclonal antibodies reduce inappropriate antibiotic use in early life and the associated negative consequences arising from microbiome changes and reduced development of antimicrobial resistance.
- Investigate whether combined implementation of vaccines and long-acting monoclonal antibodies may provide clinical benefit for specific populations.

Antiviral agents for RSV disease

- Investigate broader applicability of the findings for the ziresovir Phase III trial, which was only conducted in China, by conducting studies across diverse global populations and enrolling infants earlier in their RSV disease, potentially using internationally recognized endpoints for clinical efficacy.
- Conduct acceptability studies for the paediatric formulation of ziresovir.
- Optimize trial design for antiviral agents by setting principles for study design so that completed studies can provide meaningful information on clinical benefit. This relates particularly to:
  - defining suitable and meaningful study endpoints that can easily be interpreted by and translated into clinical practice;
  - developing and implementing standardized and simplified scoring systems for severity to be used in clinical trials;
  - understanding the optimal timing of treatment initiation, since promoting earlier recruitment in studies investigating antiviral agents for RSV may support reducing the bias on the final clinical effect; and
  - designing large-scale, multicountry studies with appropriate sample sizes, including children from low- and middle-income countries.
- Study antiviral agents and the generation of any natural antibodies in breakthrough infections among children who were already immunized with long-acting monoclonal antibodies or who were born to mothers receiving the RSVPreF vaccine to ensure that the results translate into real-world effectiveness and evidence.
- Evaluate whether antiviral agents differ in how effectively they treat people with RSV A and B.

[a] As identified by WHO's Strategic Advisory Group of Experts on Immunization *(11)*.



Conclusions and next steps

The PADO for RSV meeting brought together academic researchers, clinical experts, implementing partners and other key stakeholders involved in research and development to reach consensus on the first-ever PADO priority list for RSV, which contains three key therapeutics to be developed in the short term, including two long-acting monoclonal antibodies meeting WHO preferred product characteristics targets (including for programmatic suitability and access) and one antiviral agent in a child-appropriate dosage form.

The overall outcome of the exercise will be widely disseminated via multiple opportunities for engagement with regulators, industry, funders, civil society and the general public.

Finally, the WHO Department of Immunization, Vaccines and Biologicals and the WHO Department of Maternal, Newborn, Child and Adolescent Health and Ageing will use existing mechanisms to follow up on some of the technical discussions in the areas given priority, including identified research priorities. Where needed, the GAP-f network and its working groups will be leveraged to advance and accelerate the investigation, development and introduction of priority products.

PADO-RSV priority list	PADO-RSV watch list
Nirsevimab[a] **Clesrovimab**[a] [a]In a prefilled syringe with an autodisable feature or vial presentation plus autodisable syringe, in addition to a temperature monitor, meeting the WHO preferred product characteristics targets for critical programmatic suitability and access.	**TNM001** meeting the WHO preferred product characteristics targets for critical programmatic suitability and access
Ziresovir 10 mg (enteric coated pellets in single capsule or alternative oral solid forms that can be dispersed or dissolved)	**All oral antiviral agents currently in clinical development** (zelicapavir, EDP 323, S-337395, obeldesivir and deuremidevir hydrobromide)

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Annex 1. Agenda

Tuesday, 8 April 2025		
Welcome and introduction	Martina Penazzato (WHO)	13:00–13:05
Paediatric drug optimization (PADO) for RSV: meeting objectives	Tiziana Masini (WHO)	13:05–13:15
Epidemiology and current WHO policies	Wilson Were, Erin Sparrow Jones (WHO)	13:15–13:30
Stakeholder perspectives to inform the priority-setting exercise		
Clinical perspective	Alfredo Tagarro (PENTA)	13:30–13:40
Country experience in introducing nirsevimab	Tavitiya Sudjaritruk (Chiang Mai University, Thailand)	13:40–13:50
Q&A	All	13:50–14:05
Pipeline analysis		
Pipeline analysis: monoclonal antibodies	Erin Sparrow Jones (WHO)	14:05–14:20
Pipeline analysis: antiviral agents	Manuel Gijón (Hospital Universitario 12 de Octubre, Spain), Pablo Rojo (PENTA)	14:20–14:35
Access barriers and opportunities to inform the priority-setting exercise	Sébastien Morin (Medicines Patent Pool)	14:35–14:45
Landscaping for monoclonal antibodies manufacturing	Mina Adel (Africa Centres for Disease Control and Prevention)	14:45–14:55
Q&A	All	14:55–15:10
Closing and towards day 2	Martina Penazzato (WHO)	15:10–15:15

Thursday, 10 April 2025		
Introduction and objectives of day 2	Tiziana Masini (WHO)	13:00–13:05
Preferred product characteristics for monoclonal antibodies as a tool to guide priority-setting	Erin Sparrow Jones (WHO)	13:05–13:15
Breakout sessions		
Group 1: Monoclonal antibodies • Priority-setting against WHO preferred product characteristics • Consensus on product presentation	Moderator: Erin Sparrow Jones (WHO) Rapporteur: Pablo Rojo Conejo (PENTA)	13:15–14:25
Group 2: Antiviral agents • Priority-setting • Research priorities	Moderator: Tiziana Masini (WHO) Rapporteur: Heather Zar (University of Cape Town)	
Report back	Rapporteurs	14:25–14:45
Plenary	All	14:45–15:15
Review of overall PADO outcomes	Yasir Bin Nisar (WHO)	15:15–15:25
Wrap-up and next steps	Martina Penazzato (WHO)	15:25–15:30

Annex 2.
List of participants

Mina Adel	Africa Centres for Disease Control and Prevention, Ethiopia
Louis Bont	University Medical Center Utrecht, Netherlands (Kingdom of the)
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