REPORT OF ACTIVITIES OF
THE ADVISORY GROUP ON
BLOOD REGULATION, AVAILABILITY, AND SAFETY
(AG-BRAS)

2021-2025

List of AG BRAS Members

Name	Country	Membership Period
1. Dr Arwa Zakariya AL-RIYAMI	Oman	June 2021- August 2025
2. Dr Justina Kordai ANSAH	Ghana	June 2021- August 2025
3. Dr Noryati BINTI ABU AMIN	Malaysia	June 2021- August 2025
4. Dr Ubonwon CHAROONRUANGRIT	Thailand	June 2021- August 2025
5. Ms Ebele Perpetua ANTO	Nigeria	June 2021- August 2025
6. Dr Anneliese HILGER	Germany	June 2021- August 2025
7. Professor Salwa Ibrahim HINDAWI	Saudia Arabia	June 2021- August 2025
8. Dr Alan KITCHEN	UK	June 2021- August 2025
9. Dr Cheuk-Kwong LEE	Hong Kong	June 2021- August 2025
10. Dr Marwa MOHSEN NASER FAG EL NOUR	Egypt	June 2021- August 2025
11. Ms Linda Gracious MUDYIWENYAMA	Zimbabwe	June 2021- August 2025
12. Dr Guy RAUTMANN	Germany	June 2021- August 2025
13. Dr Masahiro SATAKE	Japan	July 2024 - June 2026
14. Dr Christian SCHAERER	Switzerland	June 2021- August 2025
15. Professor Ratti Ram SHARMA	India	June 2021- August 2025
16. Professor Sitalakshmi SUBRAMANIAN	India	June 2021- August 2025
17. Dr Jean Baptiste TAPKO	Cameroon	June 2021- August 2025
18. PhD FRC Path StephenTHOMAS	UK	July 2024 - June 2026
19. Dr Teguh TRIYONO	Indonesia	June 2021- August 2025
20. Dr Elizabeth VINELLI	Honduras	June 2021- August 2025
21. Dr Silvano WENDEL	Brazil	June 2021- August 2025
22. Professor Erica WOOD	Australia	June 2021- August 2025
23. Dr Hasan Abbas ZAHEER	Pakistan	June 2021- August 2025
24. Professor Yong Ming ZHU	China	June 2021- August 2025

Name	Country	Membership Period
Dr Nicole VERDUN	USA	June 2021- August 2023
Dr Paul MCKINNEY	Ireland	June 2021- January 2023
Mr Eric PARENT	Canada	June 2021- May 2022
PhD Anne Frattali EDER	USA	July 2024 - January 2025

I. DEVELOPMENT OF THE ADVISORY GROUP ON BLOOD REGULATION, AVAILABILITY, AND SAFETY (AG BRAS)

Medicinal products derived from human blood and plasma donations - such as whole blood, blood components for transfusion, and plasma-derived medicinal products (PDMPs) - are essential to healthcare and are vital for achieving universal health coverage. Moreover, safe, effective, and quality-assured blood products play a crucial role in improving and saving millions of lives each year. To ensure consistent access to these products, a well-functioning national blood regulatory system is necessary. A strong national and regional blood service, supported by a competent blood regulator, along with effective hemovigilance and pharmacovigilance systems to monitor the safety of blood donations and products, is key to strengthening the capacity to address emerging infectious threats and to ensure access for patients to safe, effective, and quality-assured blood products. Progress in blood regulation and availability has been slow in many regions of the world, with a significant disparity between higher-income and lower-income countries in access to safe, effective, and quality-assured blood products. In response to this situation, WHO has decided to establish an Advisory Group for Blood Regulation, Availability, and Safety (AG-BRAS) to support the technical advisory functions of the WHO Blood Products Programme. This group plays a key role in scaling up the implementation of WHO policies and strategies to strengthen blood systems and promote universal access to safe, effective, and quality-assured blood products worldwide.

The AG BRAS was established by posting a "Call for Experts", where the WHO welcomes expressions of interest from scientists, healthcare professionals, educators, and healthcare regulators with expertise in the following areas:

- blood regulatory framework, including regulation to oversee the quality and safety of blood products, medical devices, and in-vitro diagnostics that are used for the provision and transfusion of blood products.
- blood transfusion medicine, which covers blood donor recruitment and retention, blood donor selection, blood and plasma collection, blood donation testing, processing, storage, and distribution, prescribing, and pre-transfusion testing; evidence-based transfusion medicine, including patient blood management.
- hemovigilance system, pharmacovigilance for plasma-derived medicinal products or other surveillance and vigilance programs for patient and blood donor safety; surveillance and response to emerging and re-emerging blood safety threats.
- access to safe and quality-assured blood products, especially for low and middle-income countries and disadvantaged population/patient groups.

The AG BRAS functions according to its Terms of Reference are to:

1. advise on the development of WHO norms, standards, technical guidelines, and high-level strategic recommendations on ensuring the safety, quality, and availability of blood products.
2. advise on scaling up the implementation of existing WHO policies and strategies, including innovative strategies and tailored approaches; as well as strengthening the national systems for blood supply and regulation to achieve the goal of universal access to safe, effective, and quality-assured blood products.
3. provide scientific assessment of current and emerging threats to the safety and availability of blood and blood products; advise on the recommended measures and actions to be taken by the Member States in preparedness for and in response to the emerging public health threats.

Twenty-five candidates out of 109 were selected, ensuring a balance in terms of region, background knowledge, and gender. At the first online meeting of the AG BRAS on July 22, 2021, the Director of Health Products Policy and Standards at WHO Headquarters announced the appointment of the AG BRAS chair. During this first meeting, the selection process for co-chair was also discussed, and all members agreed to have a call for interest among AG BRAS members. The same process was also applied for selecting the chair and co-chair for the next period.
The Chair and co-chair of the AG BRAS and their period of position are as follows:

Chair	Co-Chair	Period
Dr Anneliese HILGER	Prof Yong Ming ZHU	2021-2023
Dr Christian SCHAERER	Prof Erica WOOD	2024-2025

II. AG BRAS WORKPLAN

In line with the AG BRAS Terms of References (attachment 1), AG BRAS developed the work plan for 2021-2022 (attachment 2), 2023-2024 (attachment 3), which is the continuation of the work plan 2021-2022, and the work plan for 2025-2026 (attachment 4). To implement the work plan, several working groups were established.

III. AG BRAS MEETINGS

AG BRAS regularly holds online meetings every three to four months and a face-to-face meeting every two years. The first in-person meeting took place in 2023; however, due to budget constraints, the planned 2025 face-to-face meeting could not be held.

Here is the list of AG BRAS Meetings in 2021-2025:

Year	s	Type of the Meeting	Minutes of Meeting
2021	22 July 2021	Online meeting	Attachment 5
	2 September 2021	Online meeting	Attachment 6
	4 November 2021	Online meeting	Attachment 7
2022	10 February 2022	Online meeting	Attachment 8
	12 May 2022	Online meeting	Attachment 9
	14 September 2022	Online meeting	Attachment 10
	7 December 2022	Online meeting	Attachment 11
2023	7-8 March 2023	Face-to-face meeting	Attachment 12
	15 June 2023	Online meeting	Attachment 13
	4 October 2023	Online meeting	Attachment 14
2024	23 January 2024	Online meeting	Attachment 15
	16 April 2024	Online meeting	Attachment 16
	16 July 2024	Online meeting	Attachment 17
	17 September 2024	Online meeting	Attachment 18
	10 December 2024	Online meeting	Attachment 19
2025	25 March 2025	Online meeting	Attachment 27
	2 July 2025	Online meeting	Attachment 28
	2 September 2025	Online meeting	Attachment 29
	15 December 2025	Online meeting	Attachment 30

IV. ACHIEVEMENT OF THE AG BRAS WORKS IN 2021-2025

Working Group 1

Working Group 1 aims to review the WHO documents repository related to blood, chaired by Dr. Silvano Wendel. This working group has sorted a total of 94 WHO documents provided by BTT according to different subjects and distributed total AG-BRAS members, who had the responsibility to provide initial comments about the fate of these documents. The working group completed the task in May 2022 and concluded that:

- 25 documents: no need for update.
- 50 documents: need an update. Further work is needed by the group to identify documents that need priority updating.

- 6 documents are obsolete and are advised to be archived.
- 13 documents: no need for further actions because some are under an updating process, and some are not related to blood transfusion works.

The detailed reports from WG 1 can be found in attachments 20 and 21.

Working Group 2

Working Group 2 aims to check the compliance of the AABB fundamental standard with the WHO standard in preparation for the joint WHO-AABB project on the education of blood establishments, chaired by Dr. Elizabeth Vinelli. The working group completed the task in September 2022 and concluded that:

- The AABB Fundamental Standards could be endorsed as they are; however, it is recommended that the Quality Certificate Program include variants to account for national and regional differences.
- AABB should ensure that the Fundamental Standards are kept up to date and aligned with the regular standards.
- Combining the current AABB training modules with the WHO QMT Program may not be practical. Instead, WHO should provide a presentation within the AABB modules to introduce these materials. The QMT modules should be made available to countries participating in the pilot project.
- The group anticipates strong interest from countries in participating in the Scholarship Program for the AABB Quality Certificate. The selection process should include:
  - A list of minimum criteria provided by AABB
  - Endorsement from governmental authorities
  - A review process conducted by WHO country and regional offices
- The AABB Quality Certificate should be considered a first step toward meeting quality standards. As it is currently based solely on a paper audit, efforts should be made to incorporate on-site visits in the future.

The detailed report of this working group can be found in attachment 22. Unfortunately, the joint WHO-AABB project on the education of blood establishments cannot be conducted as planned because of limited funding from both sides, WHO and AABB.

Working Group 3

Working Group 3, chaired by Dr. Yong Ming Zhu, is focused on harmonizing definitions and terminology related to blood, with a step-by-step phased approach. In phase I, the working

group agreed upon and proposed 36 terms and definitions across 8 categories. These proposals were initially accepted in principle by the AG BRAS in September 2022 and fully ratified in December 2022. Following this, in March 2023, a face-to-face meeting was held in Geneva, where AG BRAS members engaged in thorough discussions and reaffirmed their acceptance of the proposals. On May 9, 2023, the working group presented the final report for phase I (attachment 23a) and the list of terms and measurements for phase I (attachment 23b) to the AG BRAS.

In phase II, the working group focused on 19 additional terms. During the AG BRAS meeting on April 16, 2024, the working group presented the interim report for phase II (attachment 23c) and the list of terms with proposed definitions for phase II (attachment 23d). The working group subsequently organized the terms from both phase I and phase II into a consolidated list. On July 16, 2024, AG BRAS approved the report for phase II (attachment 23e) and the updated version of the final consolidated list of terms (vf 20240718). In total, 55 terms across 9 categories were proposed and accepted during phases I and II.

Working Group 4

Working Group 4 aims to develop a strategy for disseminating and promoting the WHO documents, including the GBT+Blood, and is chaired by Dr. Jean Baptiste Tapko. The working group completed the task in September 2022 with the following recommendations:

- Prioritization and update of relevant documents
- Improve access to online versions on WHO website and use of links with the other official health organisations and blood programs
- Use of international, regional, country professional societies and WHO Collaborating centers to promote and disseminate WHO materials
- Use of webinars, meetings, conferences
- Use of electronic media

The report can be found in attachments 24a and 24b.

Working Group 5

Working Group 5 aims to develop a form to be used for reporting the blood service situation during an emergency, to develop a simpler GDBS, and to evaluate the current status of CCP in the treatment COVID-19. This WG is chaired by Dr. Sharma Rattiram.

The activity to develop a form to be used for reporting the blood situation during an emergency was completed in May 2024. The WG continued working on developing a simpler GDBS, and this activity was completed in March 2025. The detailed reports of these two activities can be found in attachments 25a and 25b.

Meanwhile, the evaluation of the current status of the CCP in the treatment of COVID-19 was pending, waiting for the finalization of the Cochrane Study.

Working Group 6

Working Group 6 aims to support the identification of essential collaborative partners in the area of blood and the promotion of virtual communication paths, e.g., social media, and is chaired by Dr. Erica Wood. This activity is ongoing.

Working Group 7

Working Group 7 aims to prepare a webinar to present the AG BRAS and its activities. This webinar was conducted on 13 December 2024. The presentation can be found in attachment 26.

Working Group 8

Working Group 8 aims to assist WHO in developing an advocacy paper regarding plasma exportation for producing PDMPs. This working group is chaired by Dr. Christian Schaerer, who, with other experts from outside AG BRAS, is involved in the drafting group. The drafting of this document with the title "Implementing cross-border transfer of domestic plasma to obtain plasma-derived medicinal products (PDMPs): Policy Guidance, was completed in Q4 2024, and the guidance was published in January 2025.

The publication link is https://iris.who.int/handle/10665/380192

Working Group 9

Working Group 9 aims to align the WHO Guidelines on GMP for Blood Establishments with PIC/S and European Good Practice Guidance for Blood Establishments and Hospital Blood Banks, and is chaired by Dr. Christian Schaerer. The activity was completed with the title of the document: Good Practices for Blood Establishments, in October 2024, and the document was adopted by the WHO Expert Committee on Biological Standardization and the WHO Expert Committee on Pharmaceutical Specifications. The document has been published, as Annex 4 of the WHO Technical Report Series: WHO Expert Committee on the Specifications for Pharmaceutical and Preparations, fifty-eight report, 2025. The report is available electronically on this link: WHO Technical Report Series 1060 2025. The report is also available on the WHO website under

publications: TRS 1060 - 58th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. Furthermore, the stand-alone publication was published in September 2025, and can be access through https://iris.who.int/handle/10665/382401. With this step, a full international alignment of GMP requirements for blood establishments is achieved.

V. RENEWAL OF AG BRAS MEMBERSHIP

The renewal of AG BRAS membership was completed in September 2025, followed by the selection of a new Chair and Co-Chair.

Of the 24 members, 19 confirmed their membership through September 2027, one member declined to continue, and two members confirmed that they would discontinue their membership in June 2026.

Prof. Erica Wood and Dr. Cheuk Kwong Lee were elected Chair and Co-Chair of AG BRAS for the term from 14 September 2025 to 13 September 2027. The online AG BRAS meeting held on 15 December 2025 was chaired by Prof. Wood. The report of this online meeting is attached (Attachment 30).

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