

4th edition

Unmet challenges in high risk hematological malignancies: from benchside to clinical practice


Turin, March 26-27, 2026

Starhotels Majestic

Scientific board:

Marco Ladetto (Alessandria)

Umberto Vitolo (Candiolo-TO)



**The role of international societies in promoting
worldwide access to modern diagnosis and treatment**

Gianluca Gaidano

Disclosures of Gianluca Gaidano

Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other
Abbvie					√	√	
AstraZeneca					√	√	
BeiGene					√	√	
Gilead	√						
Incyte					√	√	
Johnson & Johnson					√	√	
Lilly					√	√	

Role of international societies in global activities:

- **Why: the rationale in thoughts and facts**
- Now: activities already in place
- Then: potential actions to pursue

Societies bylaws: ASH

AMERICAN SOCIETY OF HEMATOLOGY

Bylaws*

ARTICLE I

Name

The name of this organization is: American Society of Hematology.

ARTICLE II

Incorporation

The Society is incorporated as a nonprofit organization for educational, scientific, and philanthropic purposes under the laws of the Commonwealth of Massachusetts under the name as designated in Article I.

ARTICLE III

Purposes

The purposes of this corporation shall be to engage exclusively in charitable, scientific, and educational activities and endeavors including specifically but not limited to promoting and fostering, among the many scientific and clinical disciplines, the exchange and diffusion of information and ideas relating to blood and blood-forming tissues and encouraging investigations of hematologic matters. No substantial part of the activities of the corporation shall consist of carrying on propaganda or otherwise attempting to influence legislation.

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Motto: ASH



Helping hematologists conquer blood diseases worldwide

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Stand for Science!

As the world's largest professional society serving clinicians and scientists around the world who are working to conquer blood diseases, ASH is fighting for hematology in the face of executive orders and other federal actions that threaten hematology research and, ultimately, the care of patients.

Join the [#Fight4Hematology](#)

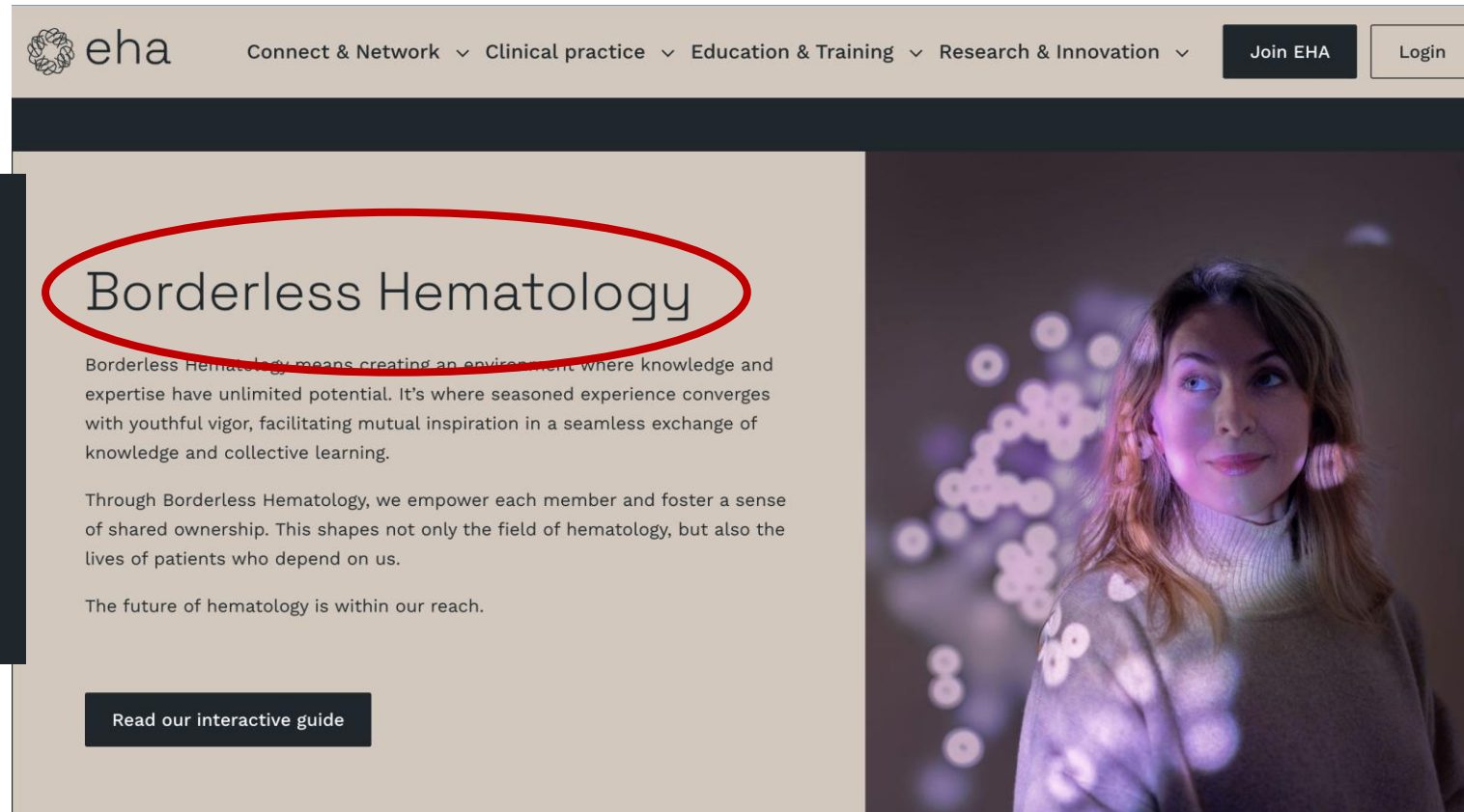
FIGHT
4 HEMATOLOGY

Scope: EHA

Compliance, plans, and reports

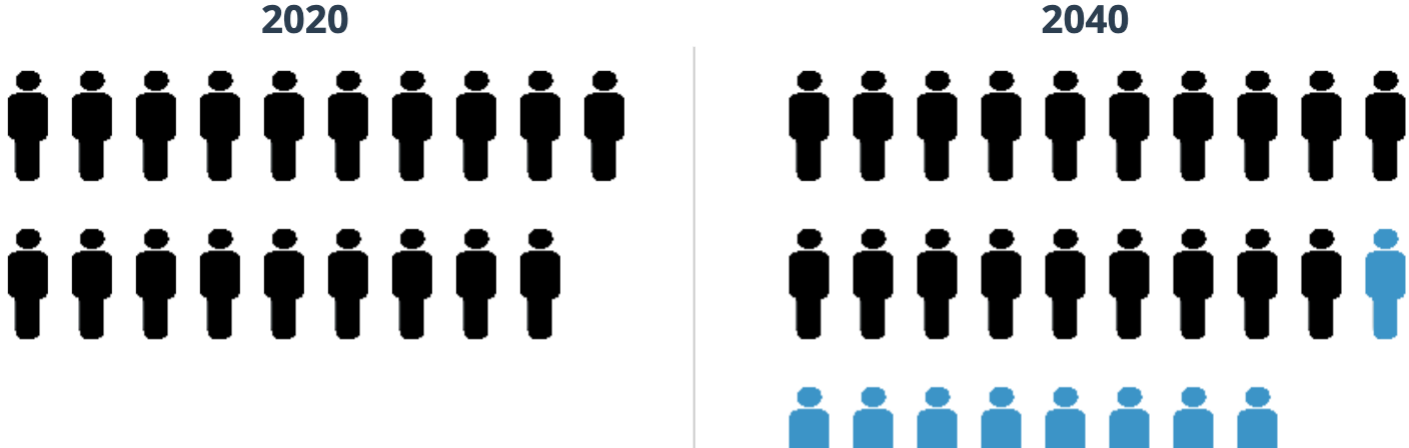
EHA is a non-governmental and not-for-profit membership organization. We're guided by our mission to mobilize professionals, share knowledge, connect interests, and advocate for hematology in Europe —and beyond.

We have a broad range of protocols and processes in place to ensure we adhere to the highest standards of governance, as demanded by our members.



The screenshot shows the EHA website header with the logo and navigation menu: "Connect & Network", "Clinical practice", "Education & Training", and "Research & Innovation". There are "Join EHA" and "Login" buttons. The main content area features a section titled "Borderless Hematology" (circled in red). Below the title is a paragraph: "Borderless Hematology means creating an environment where knowledge and expertise have unlimited potential. It's where seasoned experience converges with youthful vigor, facilitating mutual inspiration in a seamless exchange of knowledge and collective learning." This is followed by another paragraph: "Through Borderless Hematology, we empower each member and foster a sense of shared ownership. This shapes not only the field of hematology, but also the lives of patients who depend on us." and a third paragraph: "The future of hematology is within our reach." A button labeled "Read our interactive guide" is positioned at the bottom of this section. To the right of the text is a photograph of a woman with long hair, wearing a light-colored sweater, looking slightly to the side. The background of the photo is dark with bokeh light effects.

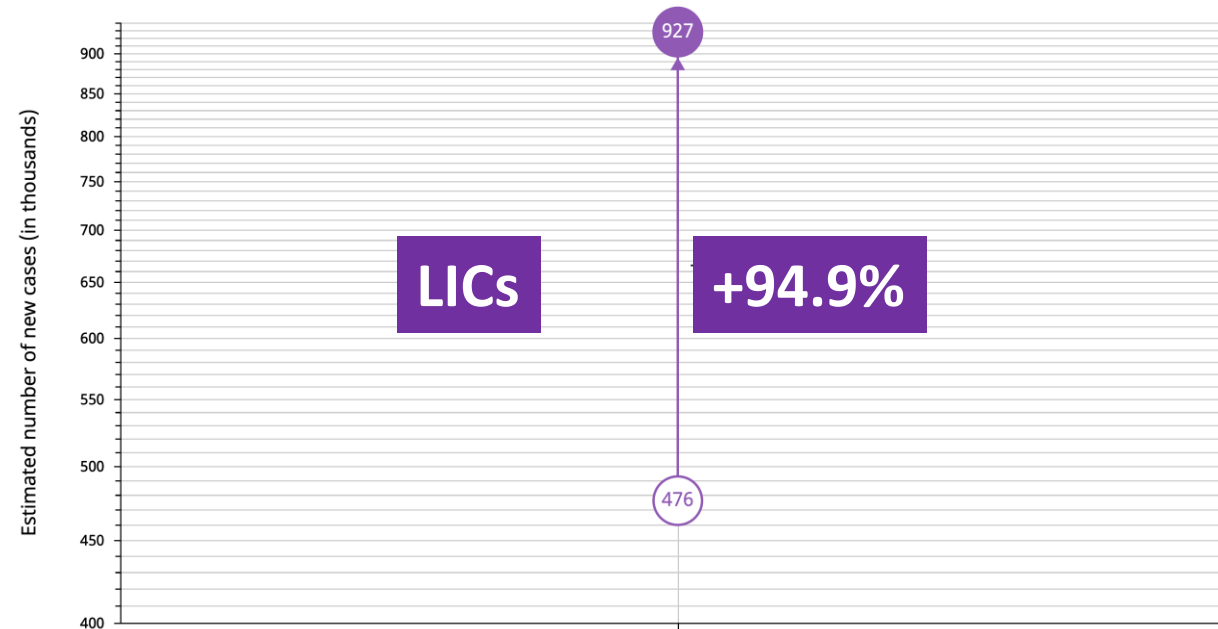
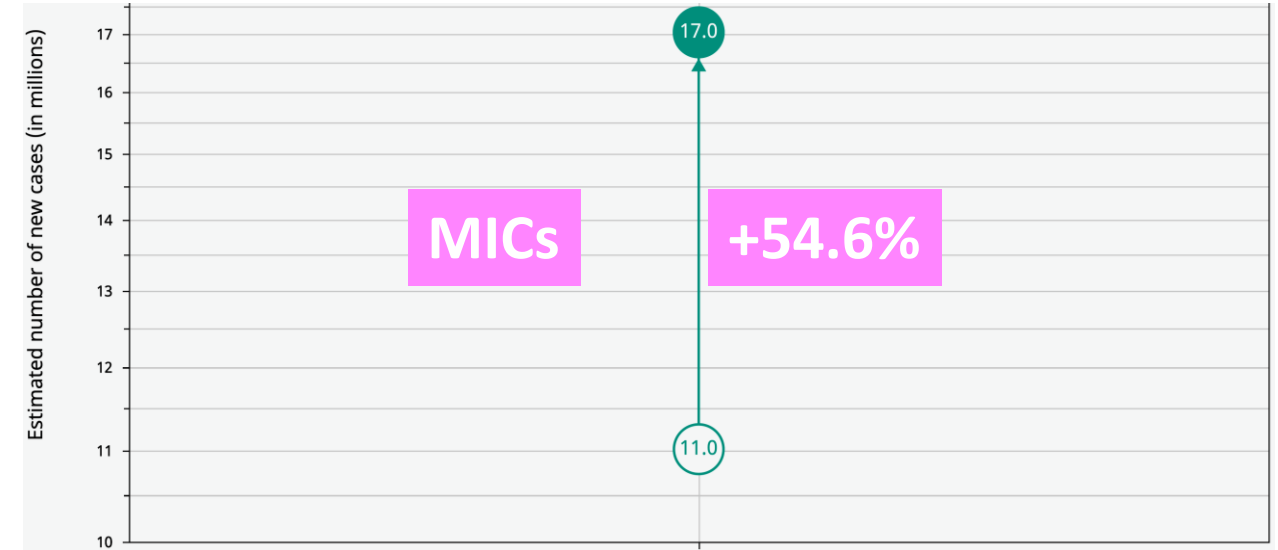
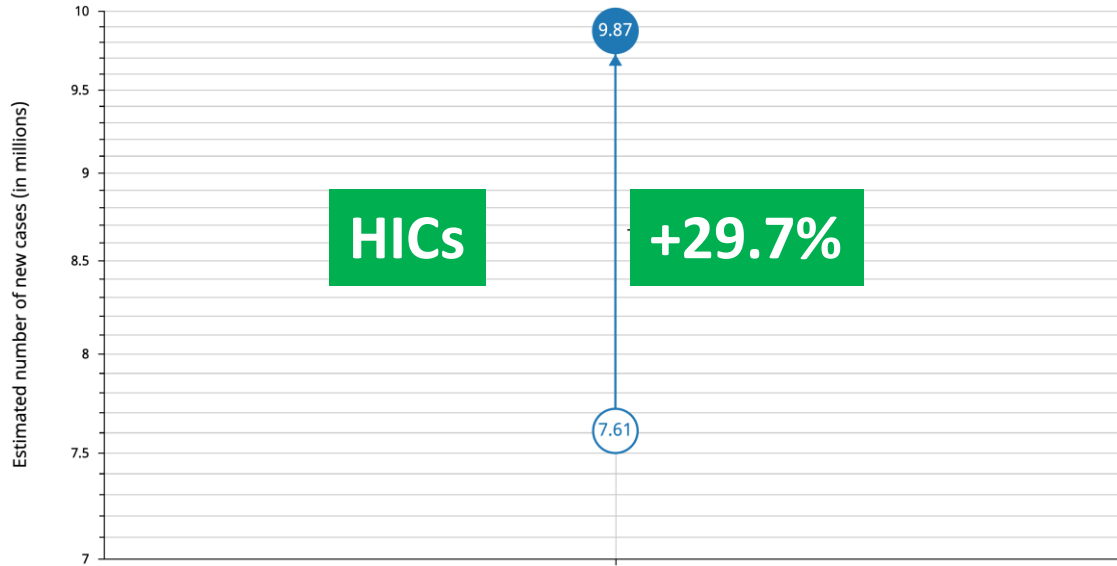
GLOBOCAN cancer estimates for 2040: New cancer cases



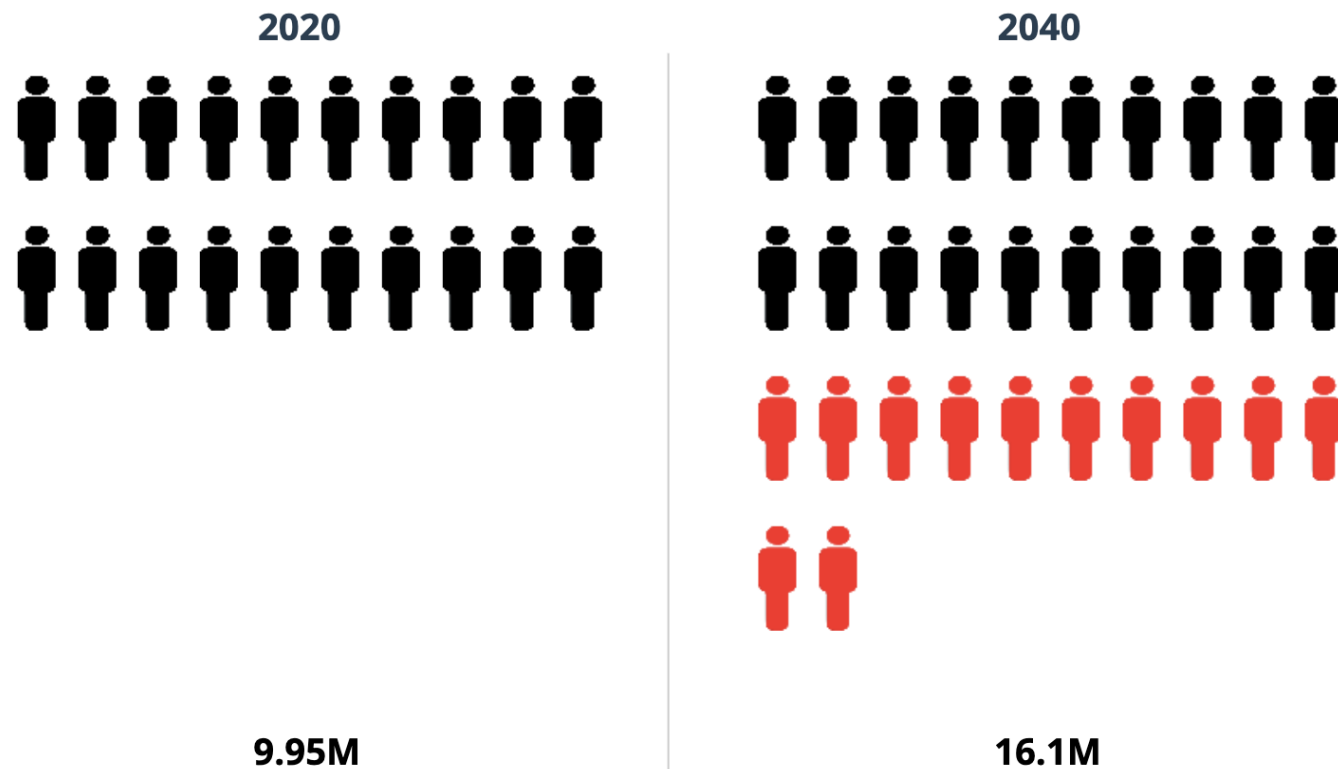
 = 1 000 000  Demographic changes

Cancer global incidence is expected to rise by 47.2% between 2020 and 2040

GLOBOCAN: Estimated increase of new cancer cases from 2020 to 2040 in HICs, MICs and LICs



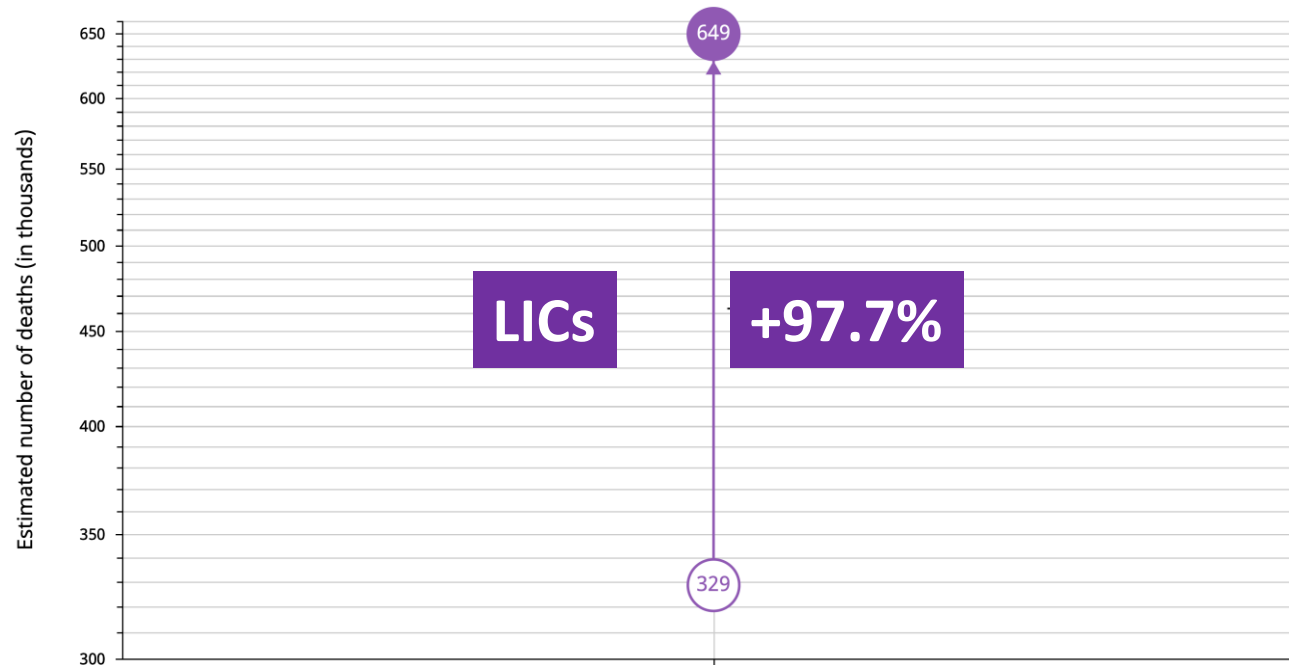
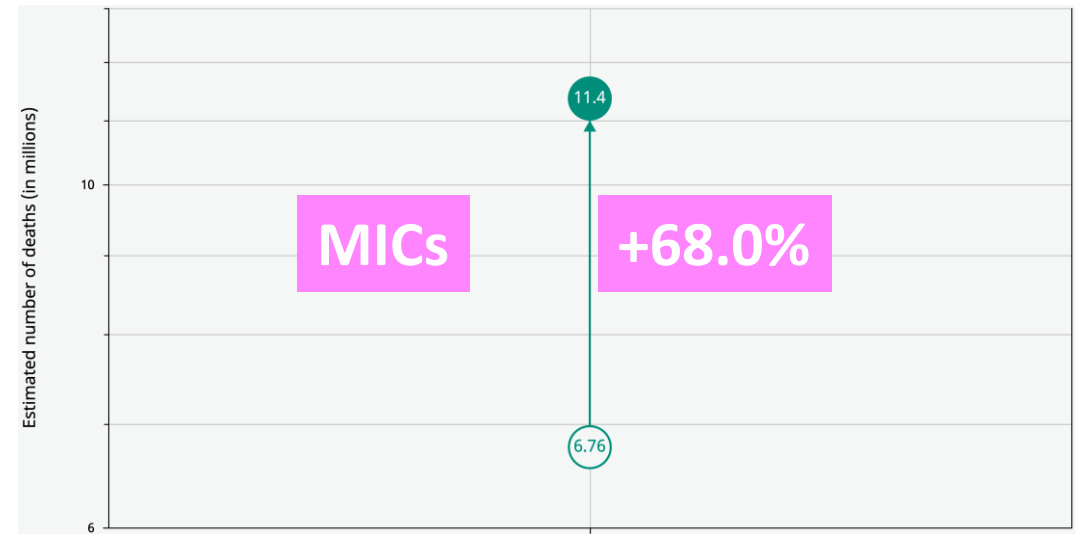
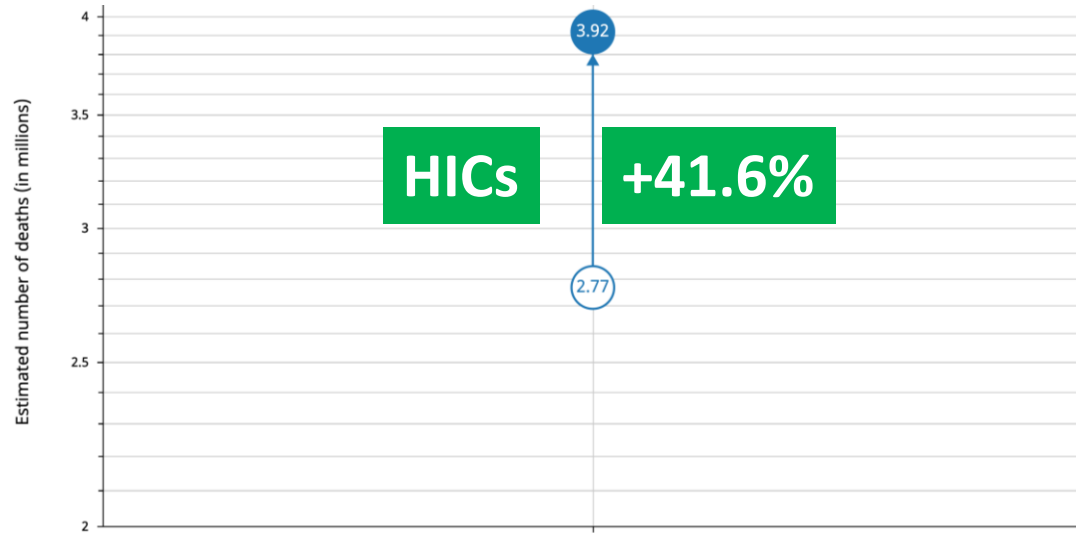
GLOBAL cancer estimates for 2040: Cancer deaths



 = 500 000  Demographic changes

A 61.8% increase of cancer global mortality is expected between 2020 and 2040

GLOBOCAN: Estimated increase of cancer deaths from 2020 to 2040 in HICs, MICs and LICs



Role of international societies in global activities:

- Why: the rationale in thoughts and facts
- **Now: activities already in place**
- Then: potential actions to pursue



GLOBAL INITIATIVES

AFRICAN VISITOR TRAINING PROGRAM - STOSSEL AWARD

This award acknowledges Dr. Thomas P. Stossel's impactful career and deep commitment to improving hematology patient care in Africa, reflecting his outstanding achievements and enduring legacy in the field of hematology.

GLOBAL RESEARCH AWARD

This award works to support future international scientific leaders, increase capacity, and nurture global collaboration among hematologists who are between the completion of training and the establishment of their independent careers.

INTERNATIONAL CONSORTIUM ON ACUTE LEUKEMIA

This initiative brings together clinical investigators from Europe, North America, and South America in the spirit of international clinical and laboratory collaboration.

HEALTH VOLUNTEERS OVERSEAS

ASH members provide targeted education and training to hematology personnel at health care institutions in low- and middle-income countries.

TRANSLATIONAL RESEARCH TRAINING IN HEMATOLOGY

This joint effort by ASH and the European Hematology Association (EHA) provides junior researchers with a unique, year-long training and mentoring experience.

CHILDREN'S INTERNATIONAL CONSORTIUM ON ACUTE LEUKEMIA (C-ICAL)

The C-ICAL initiative is a partnership between the ASH and the SickKids Caribbean Initiative that seeks to improve the care of pediatric patients with acute lymphoblastic leukemia (ALL) in the Caribbean.

INTERNATIONAL OUTREACH INITIATIVE

ASH distributes educational materials to help address hematology-related needs in low- and middle-income countries.

CONSORTIUM ON NEWBORN SCREENING IN AFRICA (CONSA)

CONSA is a network that seeks to demonstrate the benefits of newborn screening and early interventions for children with sickle cell disease in sub-Saharan Africa.

LATIN AMERICAN TRAINING PROGRAM

This program helps hematologists and hematology-related health care professionals build hematology capacity in Latin America around specific priority areas.

VISITOR TRAINING PROGRAM

Intended for talented hematologists, scientists, and laboratory staff from low- and middle-income countries, this award program provides training on a specific hematology topic or technique for up to 12 weeks.

Sharing knowledge through educational events: the model of EHA tutorials






- In collaboration with the local Hematology societies
- Usually focused on one group of diseases
- Topics chosen by the local Hematology Society in order to reflect the needs of the geographic area
- Mix of EHA and local faculty
- Based on lectures followed by interactive clinical cases
- Aiming at establishing longstanding relationships between the local Society and EHA

By collaborating with national societies from the region, tutorials aim to build long-term relationships and strengthen international cooperation, ultimately supporting healthcare professionals and improving patient care




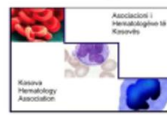






EHA tutorials as regional events



Regional, rather than national, events (e.g. Balkan region, SAARC region, MENA region, ...)

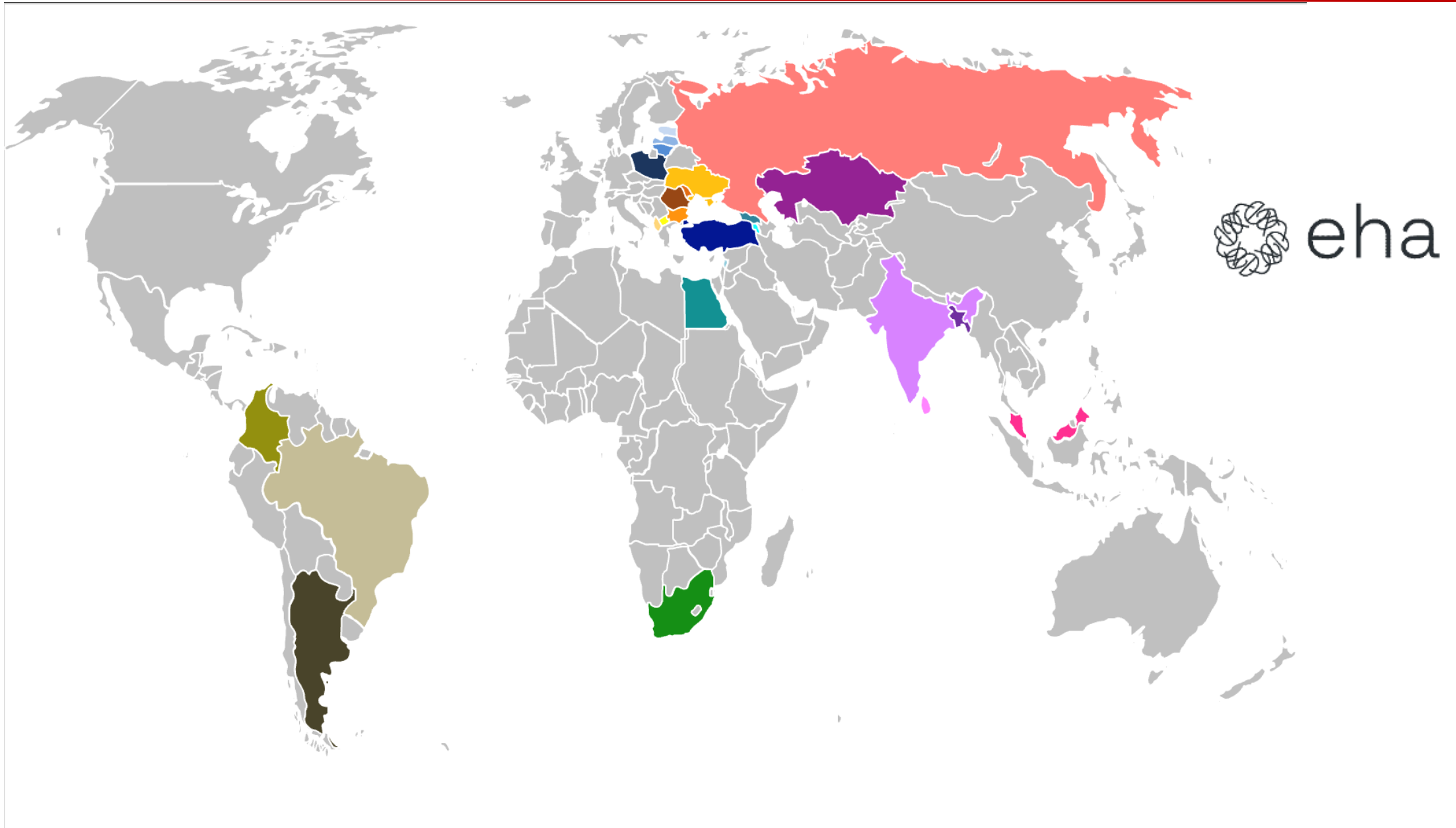
Partners

<p>Albanian Association of Hematology</p> 	<p>Bulgarian Society of Hematology</p> 	<p>Croatian Society of Hematology</p> 
<p>Kosova Hematology Association</p> 	<p>Macedonian Hematology Association</p> 	<p>Romanian Hematology Society</p> 
<p>Turkish Society of Hematology</p>  www.thd.org.tr	<p>Hellenic Society of Hematology</p> 	<p>The Hematological Section of the Serbian Health Association</p> 
	<p>Slovenian Society of Hematology</p> 	



EHA-AAH Balkan Hematology Tutorial – Tirana, 1-2 April 2022

Sharing knowledge through educational events: a map of EHA tutorials



Sharing knowledge through educational events: EHA 2025 tutorials



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EHA-SHA Balkan Hematology Tutorial 2025

Non-malignant disorders

Date: September 11-12, 2025

Location: Belgrade, Serbia

Format: Hybrid

[Contact us](#) →

EHA-HSB Hematology Tutorial

Updates on diagnosis and management of
Lymphoma and Leukemia

Date: October 3-4, 2025

Location: Dhaka, Bangladesh

Format: In-person

[More information](#) →

EHA-SAH Hematology Tutorial

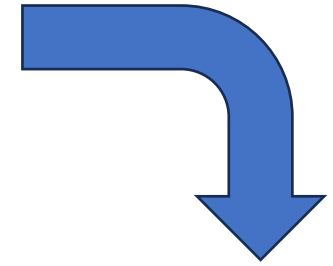
Non-malignant disorders

Date: November 7-8, 2025

Location: Mar de Plata, Argentina

Format: In-person

Official and informal times of EHA tutorials



Breaks as opportunities for discussing cases, building relationships, exchange contacts



Educational tutorials generate institutional interactions

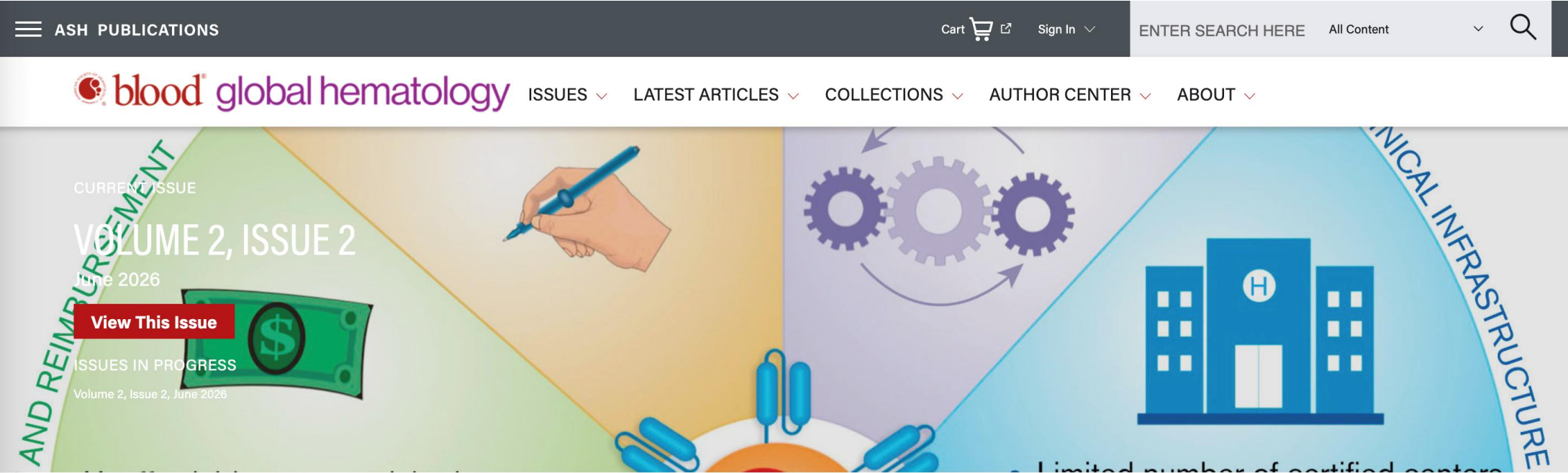


Baghdad CLL Day, Febr 20, 2026



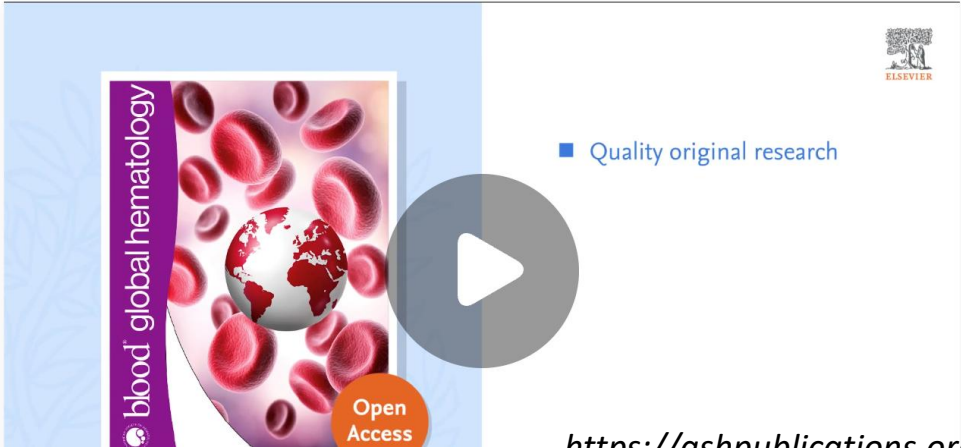
Novara, Febr 22, 2024

Publishing journals focusing on hematology in LMICs



What is *Blood Global Hematology*?

Blood Global Hematology is an open-access, peer-reviewed journal that aims to publish high-quality research, local adaptations of clinical guidelines, epidemiology and public health analyses, and opinion articles that address hematologic issues of global impact and aim to improve the lives of patients all over the world, with an emphasis on low- and middle-income countries.



<https://ashpublications.org/bloodglobal>

Development of clinical guidelines adapted to LMICs

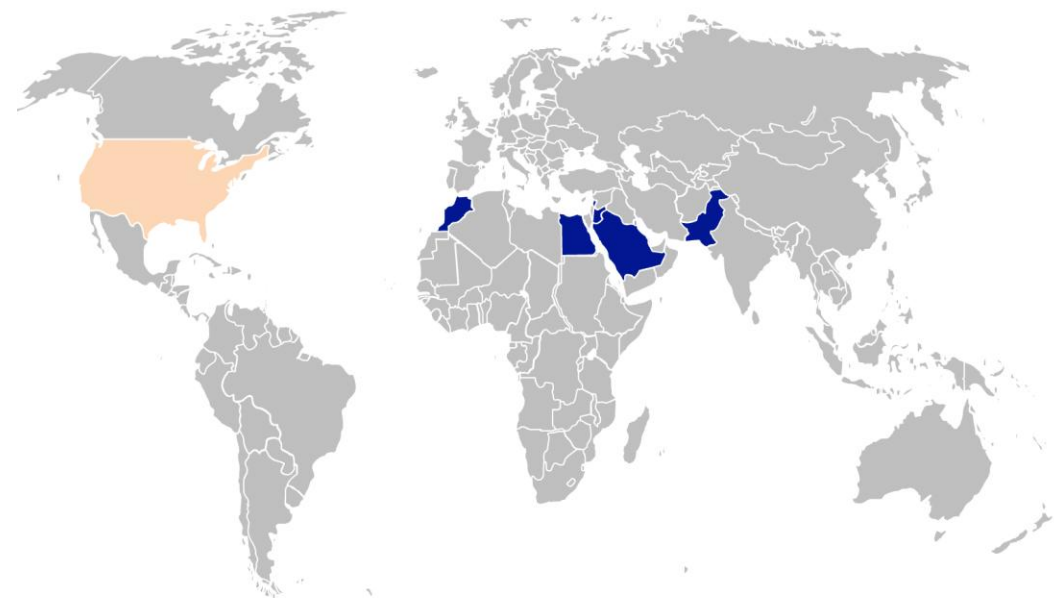


American Society of Hematology
2021 L Street NW, Suite 900,
Washington, DC 20036
Phone: 202-776-0544 | Fax 202-776-0545
bloodglobal@hematology.org

Clinical Practice Guidelines for the Diagnosis and Management of Hodgkin Lymphoma in Countries with Restricted Resources

Tracking no: BGH-2025-000339R2

Raheel Iftikhar (National University of Medical Sciences, Pakistan) Mussavir Bangash (National University of Medical Sciences, Pakistan) Ali Bazarbachi (American University of Beirut, Lebanon) Muhammad Ayaz Mir (Shifa International Hospital / Shifa College of Medicine, Pakistan) Mubarak Al-Mansour (King Abdulaziz Medical City, Saudi Arabia) Salman Arif (National University of Medical Sciences, Pakistan) Mohammad Ma'koseh (King Hussein Cancer Center, Jordan) Humera Mahmood (Nuclear Medicine, Oncology and Radiotherapy Institute, Pakistan) Walid Rasheed (King Faisal Specialist Hospital & Research Centre, Saudi Arabia) Kamran Rashid (Rashid Cancer Clinic, Pakistan) El Mehdi Mahtat (Mohamed V University, Morocco) Syed Waqas Bokhari (6. Shaukat Khanum Memorial Cancer Hospital and research center, Lahore, Pakistan, Pakistan) Azhar Rashid (Neurospinal and Cancer Care Institute, Pakistan) Mostafa Mohammed Saleh (King Faisal Specialist Hospital and Research Center, Saudi Arabia) Muhammad Sarwar (Public Sector Tertiary Care Teaching Hospital, Pakistan) Salem AlShemmari (Faculty of Medicine, Kuwait University, Kuwait) Naila Zahid (Liaquat National Hospital, Pakistan) Bushra Parveen (National University of Medical Sciences, Pakistan) Khalid Halahleh (King Hussein Cancer Center, Jordan) Mahnoor Mahnoor (Armed forces bone marrow transplant center, Pakistan) Sakina Malik (National University of Medical Sciences, Pakistan) Kashaf ad Duja Awais (National University of Medical Sciences, Pakistan) Asmaa Quessar (20 Août Hospital, Morocco) Maryam Khan (Armed Forces Bone Marrow Transplant Centre, Pakistan) Munira Moosajee (Aga Khan University Hospital, Pakistan) Muhammad Bashir (Faisalabad Cancer Center, Faisal Hospital, Faisalabad, Pakistan) Yasser Khafaga (National Cancer Institute Cairo, Egypt) Zeba Aziz (Hameed Latif Hospital, Pakistan) Riad El Fakih (King Faisal Specialist Hospital and Research Center, Saudi Arabia) Muhammad Umair Mushtaq (University of Kansas Medical Center, United States) Muhammad Nadeem (National University of Medical Sciences, Pakistan) Mahmoud Aljurf (King Faisal Specialist Hospital, Saudi Arabia) Sairah Ahmed (University of Texas MD Anderson Cancer Center, United States) Stephen Ansell (Mayo Clinic, United States)



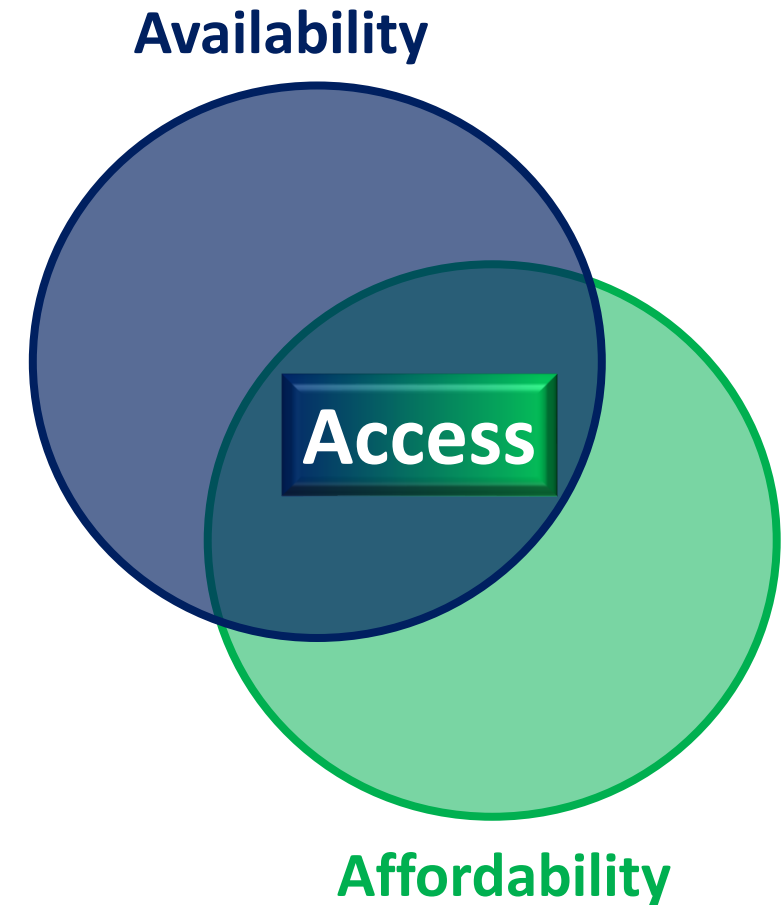
Field activities

- Together with Health Volunteers Overseas (HVO), ASH brings consultation and training to hospitals in low- and middle-income countries
- Training provided by ASH members includes rounds in the clinics, bedside consultations, classroom lectures to on-site staff and trainees, training in laboratories
- The objective of the program is to develop sustainable improvement in the management of hematology patients at these institutions and to, ultimately, enhance patient care

Role of international societies in global activities:

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- **Then: potential actions to pursue**

1. Help promoting access to essential medicines according to the WHO framework



WHO Essential Medicines List (2025): Definition

The selection and use of essential
medicines, 2025

WHO
Model List of Essential Medicines

24th list



- Essential medicines are those that satisfy the **priority health care needs of a population**.
- They are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety and comparative cost-effectiveness.
- They are **intended to be available in functioning health systems at all times**, in appropriate dosage forms, of assured quality and **at prices individuals and health systems can afford**.

WHO Essential Medicines List (2025): Targeted therapies

WHO Model List of Essential Medicines – 24th List (2025)

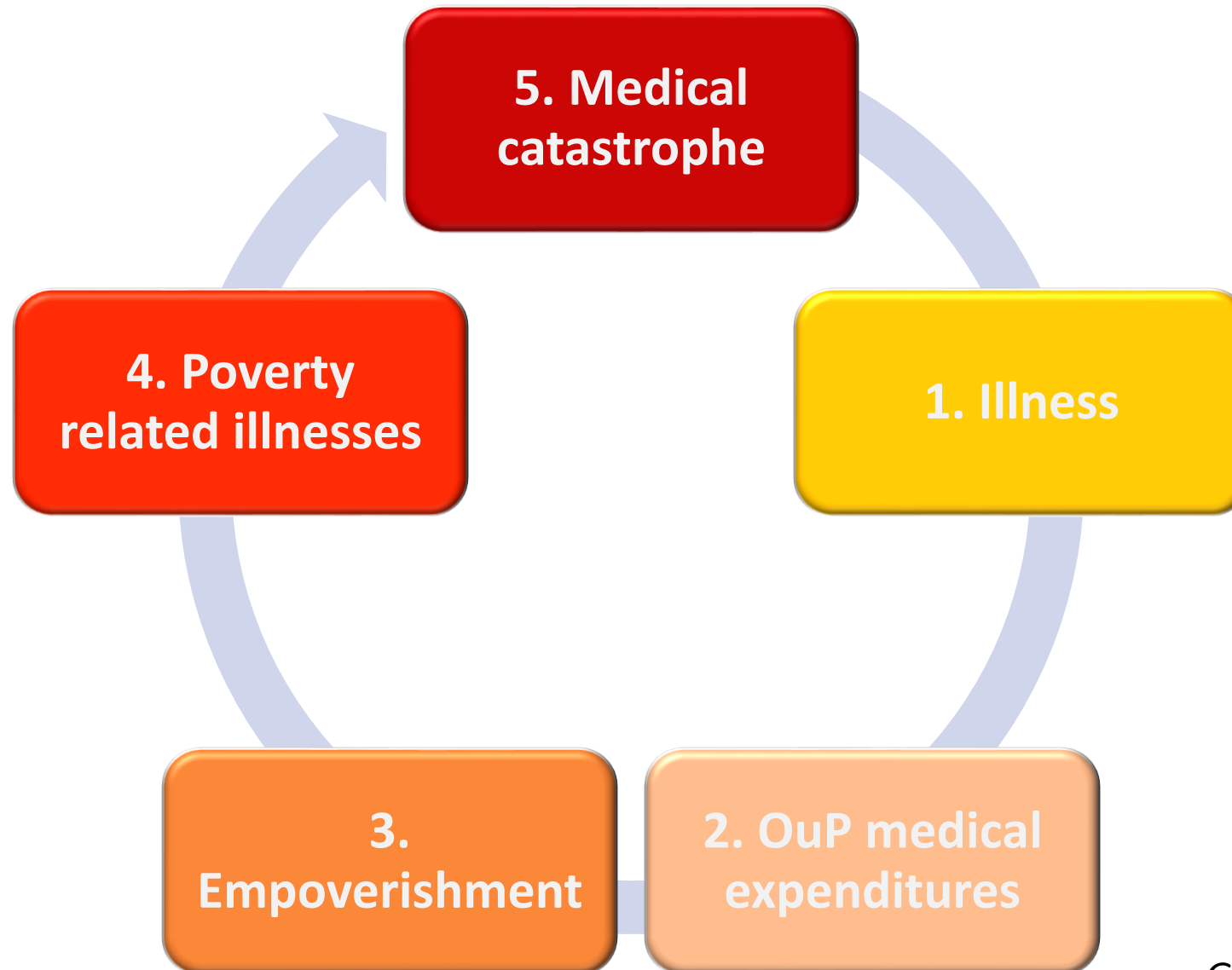
8.2.2 Targeted therapies	
Complementary List	
all-trans retinoid acid (ATRA)	Capsule: 10 mg. – Acute promyelocytic leukaemia.
bortezomib	Powder for injection: 3.5 mg in vial. – Multiple myeloma
dasatinib	Tablet: 20 mg; 50 mg; 70 mg; 80 mg; 100 mg; 140 mg. – Imatinib-resistant chronic myeloid leukaemia
<input type="checkbox"/> erlotinib Therapeutic alternatives: - afatinib - gefitinib	Tablet: 100 mg, 150 mg. – EGFR mutation-positive advanced non-small cell lung cancer
everolimus	Tablet: 2.5 mg; 5 mg; 7.5 mg; 10 mg. Tablet (dispersible): 2 mg; 3 mg; 5 mg. – Subependymal giant cell astrocytoma
<input type="checkbox"/> ibrutinib Therapeutic alternatives: - zanubrutinib	Capsule: 140 mg. – Relapsed/refractory chronic lymphocytic leukaemia/small lymphocytic lymphoma
imatinib	Solid oral dosage form: 100 mg; 400 mg. – Chronic myeloid leukaemia – Gastrointestinal stromal tumour – Philadelphia chromosome positive acute lymphoblastic leukaemia
nilotinib	Capsule: 150 mg; 200 mg. – Imatinib-resistant chronic myeloid leukaemia
rituximab* *including quality-assured biosimilars	Injection (intravenous): 100 mg/10 mL in 10 mL vial; 500 mg/50 mL in 50 mL vial. – Burkitt lymphoma – Diffuse large B-cell lymphoma – Chronic lymphocytic leukaemia – Follicular lymphoma
trastuzumab* *including quality-assured biosimilars	Powder for injection: 60 mg; 150 mg; 440 mg in vial. – Early stage HER2-positive breast cancer – Metastatic HER2-positive breast cancer

WHO Model List of Essential Medicines – 24th List (2025)

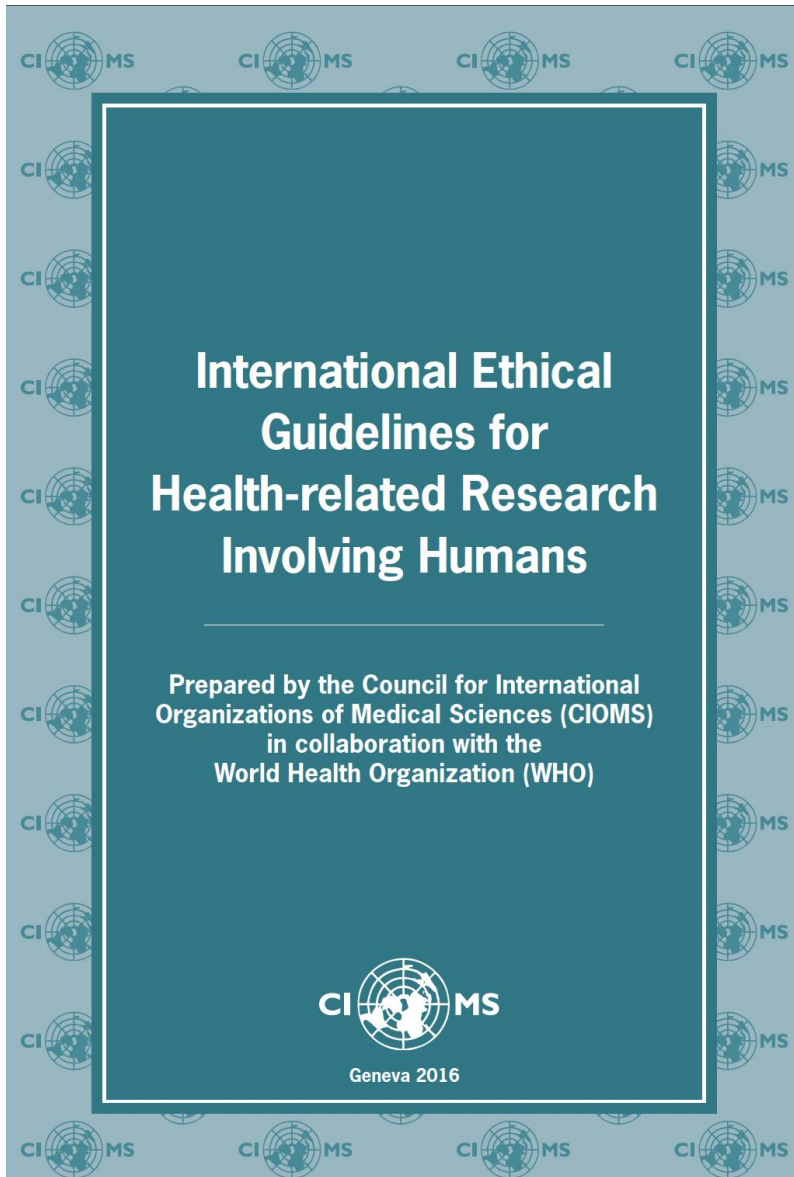
8.2.3 Immunomodulators	
Complementary List	
blinatumomab* *including quality-assured biosimilars	Powder for concentrate for solution for infusion: 35 micrograms; 38.5 micrograms in vial. – B-cell acute lymphoblastic leukemia
filgrastim* *including quality-assured biosimilars	Injection: 120 micrograms/0.2 mL; 300 micrograms/0.5 mL; 480 micrograms/0.8 mL in pre-filled syringe. Injection: 300 micrograms/mL in 1 mL vial; 480 micrograms/1.6 mL in 1.6 mL vial. – Primary prophylaxis in patients at high risk for developing febrile neutropenia associated with myelotoxic chemotherapy. – Secondary prophylaxis for patients who have experienced neutropenia following prior myelotoxic chemotherapy – To facilitate administration of dose dense chemotherapy regimens
lenalidomide	Capsule: 25 mg. – Multiple myeloma
pegfilgrastim* *including quality-assured biosimilars	Injection: 6 mg/0.6 mL in pre-filled syringe. – Primary prophylaxis in patients at high risk for developing febrile neutropenia associated with myelotoxic chemotherapy – Secondary prophylaxis for patients who have experienced neutropenia following prior myelotoxic chemotherapy – To facilitate administration of dose dense chemotherapy regimens
pembrolizumab* *including quality-assured biosimilars	Concentrate for solution for infusion: 25 mg/mL in 4 mL vial. – Metastatic cervical cancer \geq 1% PD-L1 expression ^A ^A in combination with platinum-based chemotherapy – Metastatic colorectal cancer [#] [#] as monotherapy for deficient mismatch repair (dMMR) / microsatellite instability-high (MSI-H) tumours
<input type="checkbox"/> pembrolizumab* Therapeutic alternatives*: - atezolizumab* - cemiplimab* *including quality-assured biosimilars	Concentrate for solution for infusion: 25 mg/mL in 4 mL vial. – Metastatic non-small cell lung cancer, oncogene-driver wild-type and \geq 50% PD-L1 expression ^A ^A as monotherapy
<input type="checkbox"/> pembrolizumab* Therapeutic alternatives*: - nivolumab* *including quality-assured biosimilars	Concentrate for solution for infusion: 25 mg/mL in 4 mL vial. – Metastatic melanoma ^A ^A as monotherapy
thalidomide	Capsule: 50 mg. – Multiple myeloma

<https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists>

Vicious cycle of Out of the Pocket (OuP) health systems



2. Educating to equity in clinical trials involving LMICs



Before instituting a plan to undertake research in a population or community in low-resource settings, the sponsor, researchers, and relevant public health authority must ensure that the research is responsive to the health needs or priorities of the communities or populations where the research will be conducted.

As part of their obligation, **sponsors, and researchers must also:**

- ▶ **make every effort, in cooperation with government and other relevant stakeholders, to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out, and to assist in building local research capacity.** In some cases, in order to ensure an overall fair distribution of the benefits and burdens of the research, additional benefits such as investments in the local health infrastructure should be provided to the population or community; and
- ▶ **consult with and engage communities in making plans for any intervention or product developed available, including the responsibilities of all relevant stakeholders.**

General considerations. This Guideline pertains to settings in which resources are so limited that the population may be vulnerable to exploitation by sponsors and investigators from wealthier countries and communities. The ethical standards applied should be no less stringent than they

Risk of exploitation of economically vulnerable populations

The «algebra» of clinical trial globalisation in MICs

Reasons

- Lower research costs
- Administrative convenience
- Availability of larger pools of potential participants

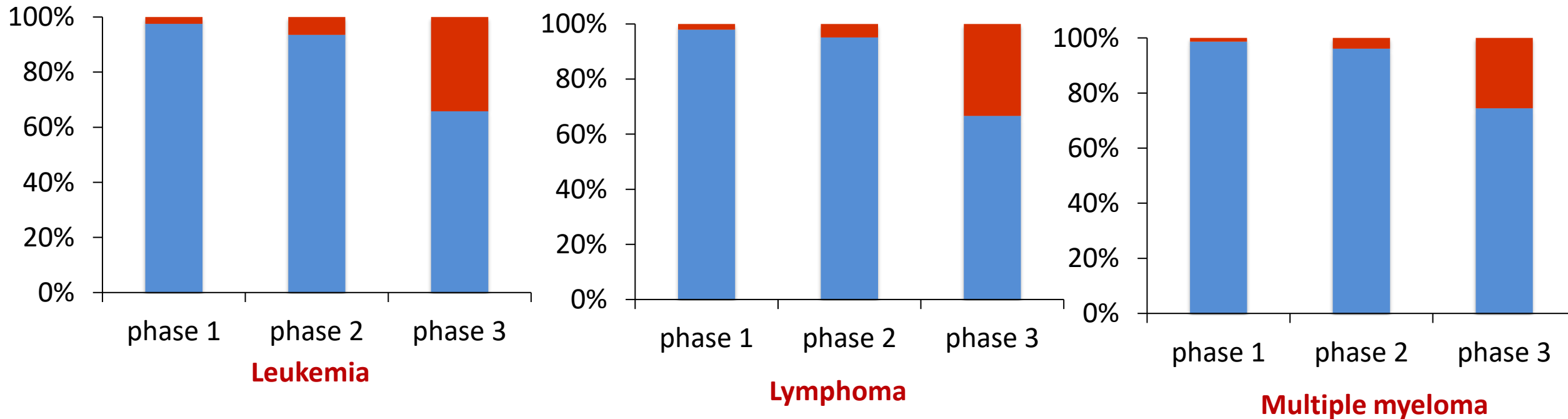
Concerns

- Acceptance *a priori* of a trial as the only option for receiving treatment
- Less stringent oversight
- Recognition of authorship to local researchers

Benefits

- Involvement of MICs in international research
- Implementation of clinical facilities
- Prompting toward request for access to drugs

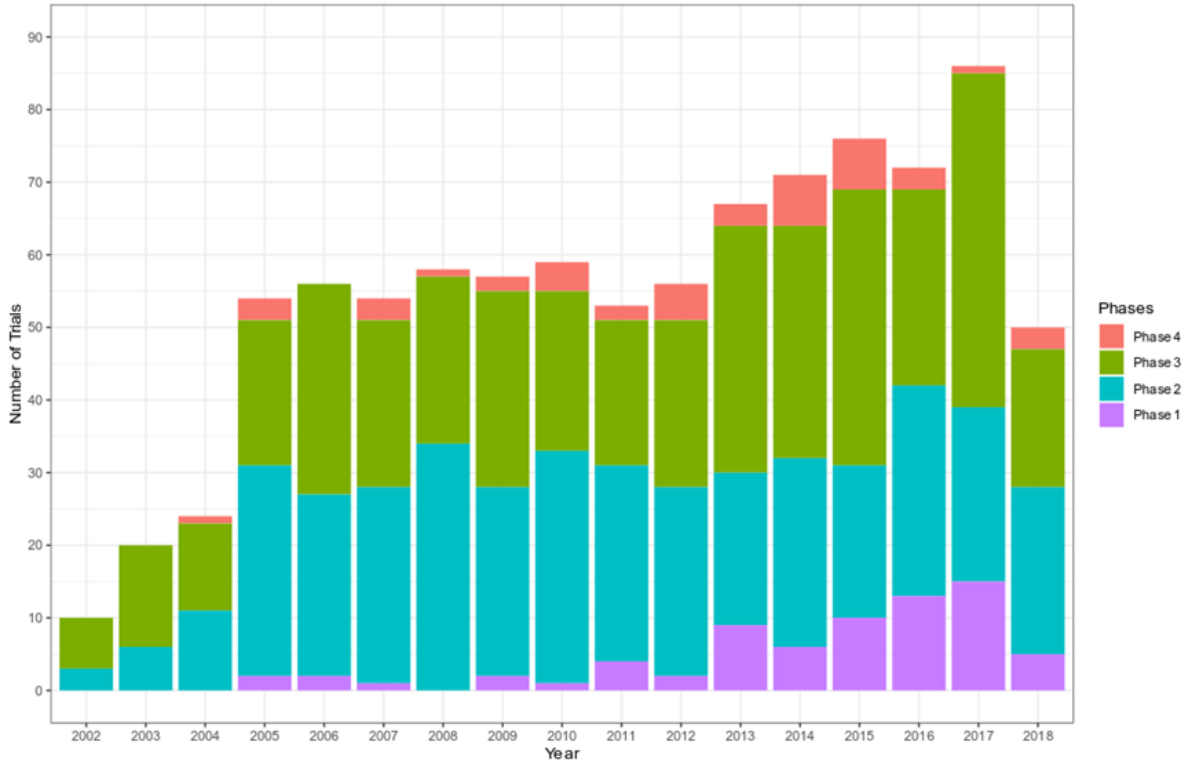
Involvement of MICs in sponsored clinical trials for leukemia, lymphoma and multiple myeloma



- 30% of phase 3 clinical trials have involved sites in MICs, including both low-middle and upper-middle income countries
- Trials run in MICs targeted all ages, including children or adolescents and the elderly

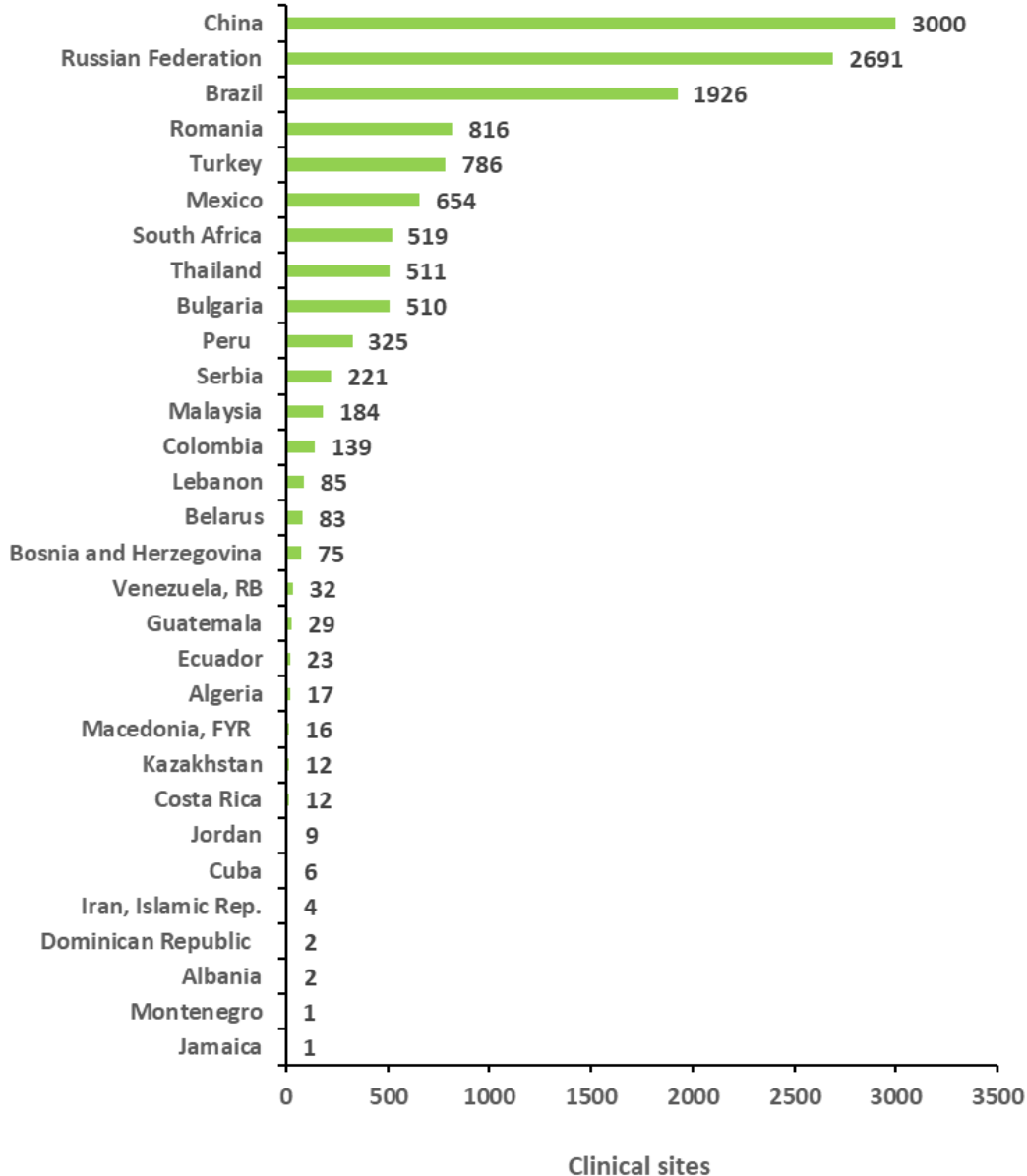
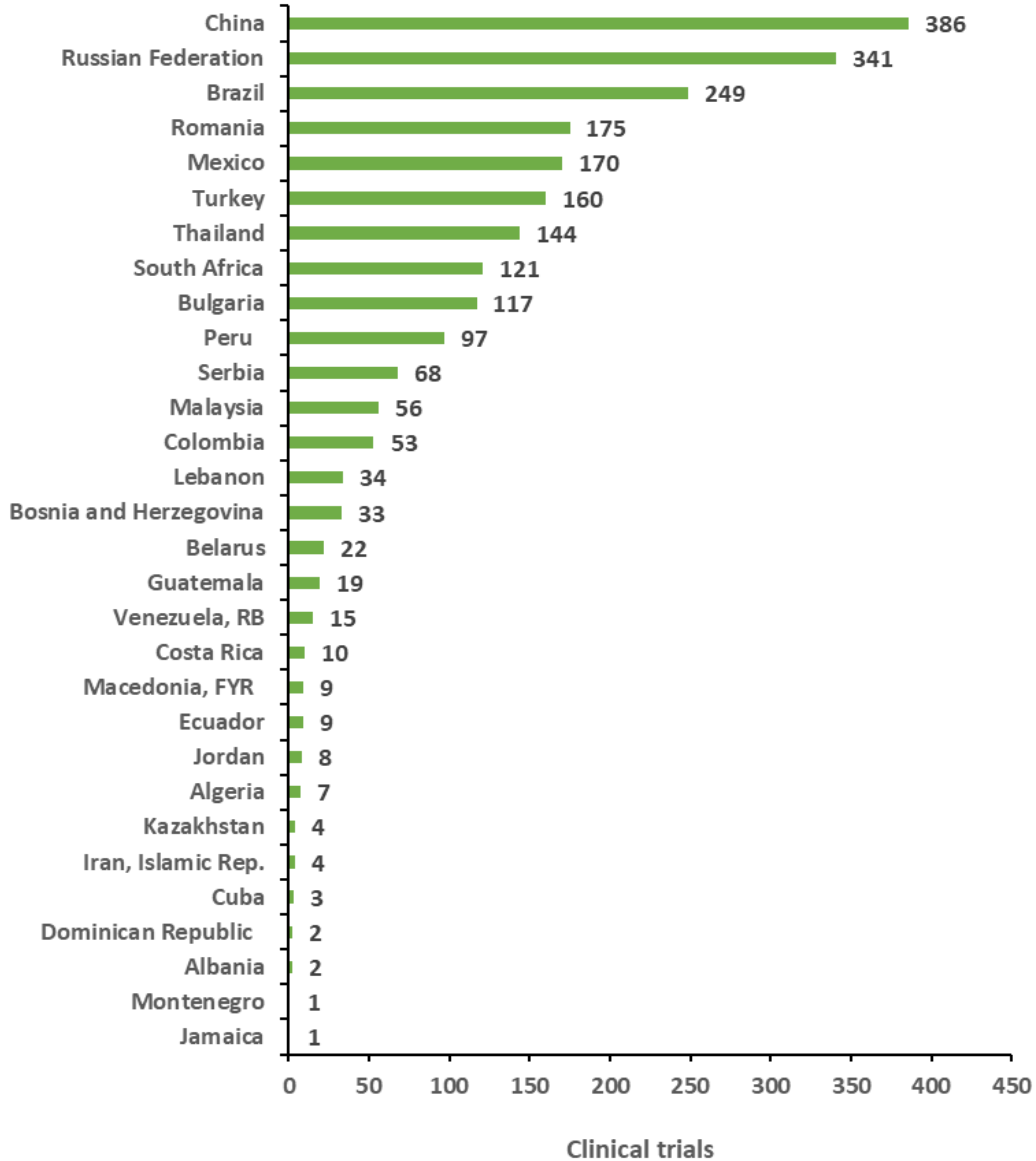
Global distribution of industry-sponsored breast, lung and colon cancer clinical trials

Phases	N. Trials	Involving MICs	%	HICs only	%	p value
I	950	72	7.58%	878	92.42%	<0.001
II	2,450	390	15.92%	2,060	84.08%	<0.001
III	688	416	60.47%	272	39.53%	<0.001
IV	89	45	50.56%	44	49.43%	<0.001
Total	4,177	923	22.10%	3,254	77.90%	

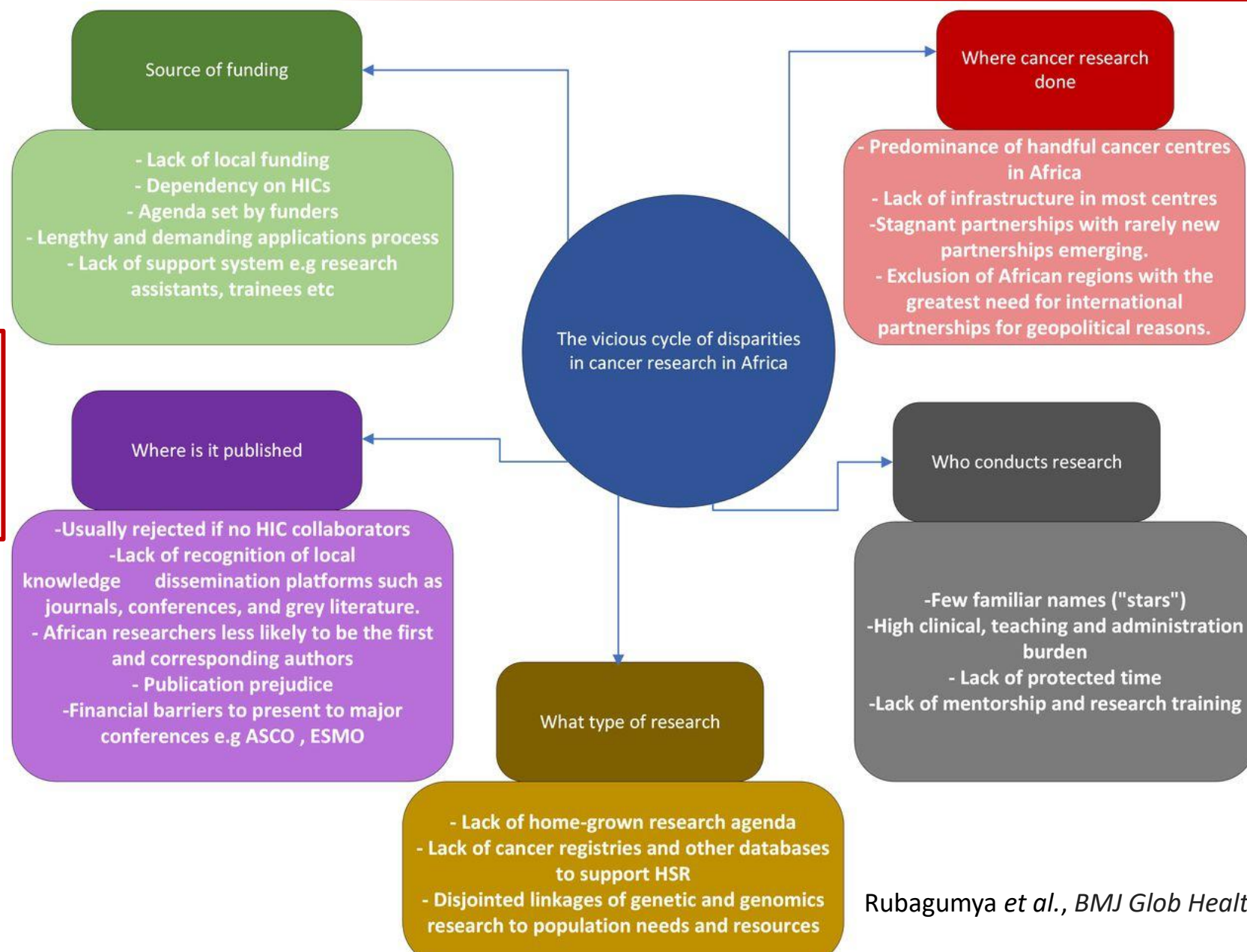


- MICs are significantly involved in phase III and phase IV interventional clinical trials
- No trials were conducted in lower-income countries (LICs) until 2018
- The number of trials in MICs has been constantly rising in the last two decades

Distribution of industry-sponsored breast, lung and colon cancer clinical trials in U-MICs



3. Fostering recognition of local researchers in cancer research



More than 30% of HIC-led oncologic RCTs that included LMIC patients did not list LMIC authors in the publications

Authorship inequalities in sponsored clinical trials for cancer

- In the study period (up to March 30, 2024), 40% (109 out of 275 articles) of publications from trials involving both HIC and MIC sites did not have a single MIC author
- Conversely, 78% (21 out of 27 articles) of publications from trials conducted exclusively in MICs had MIC first, middle, and last authors
- The insufficient representation and inclusion of MIC authors is suggestive of a structural imbalance in authorship in global oncology
- Scientific societies of HICs should actively advocate for more fairness toward their peers in MICs
- As this issue seems to have only recently been raised in the specific field of oncology, more research as well as awareness-raising are needed

Summing up

- Cancer incidence and mortality are expected to rise at a fast pace in LMICs in the next decade
- International hematological societies have an important role in fostering hematology in underprivileged areas of the globe
- Initiatives already in place include education, publishing, developing adapted guidelines, field activities and others
- Unmet needs include promoting access to innovative medicines, equity in clinical trials and recognition of local researchers

**University of Eastern Piedmont
Novara**

Anil Babu Payedimarri
Samir Mouhssine

**Institute for Tropical Medicine
Antwerp/Anverse**

Raffaella Ravinetto
Saleh Aljadeeah
Pierre Massat

**Catholic University of the Sacred Heart
Milan**

Pier Davide Guenzi

gianluca.gaidano@uniupo.it

Benefit sharing

- The concept of benefit sharing deals with the concern of what participants and communities ought to gain as a result of their participation in biomedical research
- Research sponsors gain generalizable knowledge and profit from interventions that have been proven effective
- Ethically, participants/communities should also gain something in return for contributing to research endeavor

➤ **Benefit fairly shared with participants and communities**

- Upgrade diagnostic/clinical capacity
- Access to interventions developed by research
- *Prior dialogue with industry, health authorities, advocacy*
- *An explicit “access” plan*
- **Data sharing** beyond a specific study or consortium
- **Ownership of samples** exported abroad (ex. Ebola)

Declaration of Helsinki (2013)

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

This principle reaffirmed by all versions of the Declaration reflects the **need for a direct link between obtainment of scientific results and achievement of health benefits in vulnerable groups**

Economical poverty is a criterion for vulnerability in medical research

- the **Belmont Report** includes among vulnerable groups the minorities and the economically disadvantaged.
- In poor countries, **vulnerability** is often linked to poverty, social exclusion and lack of access to health care, and **may drive populations towards participation in clinical trials as a way to secure otherwise unavailable free access to care**

The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979; Pare' Toe et al, PlosONE 2013; Ravinetto et al, Lancet Hematol 2014; Ravinetto et al, Trop Med Int Health, 2015



What needs to be improved

Awareness



Advocacy



Place Benefit Sharing as a top ethical requirement

Consistent/Succinct definition



Mesh term in PubMed



Avoid confusion with financial compensation

Legal instruments on benefit sharing would require a careful implementation process

Summing up

- Globalization of cancer research is a growing phenomenon with potential benefits for LMICs, but also risks (e.g. lack of benefit-sharing and subsequent access to medicinal product)
- An active role of MICs in clinical research with innovative medicines is beneficial provided that there is a reasonable likelihood that their populations will benefit from the research
- The shift in geographical boundaries should prompt a quest for ethically acceptable solutions rather than being perceived as an obstacle toward MICs involvement
- Regulatory and legislative measures are required to ensure the availability and affordability of innovative medicines in countries that participated in industry-sponsored trials
- Research institutions in MICs should receive adequate recognition in authorship and be empowered to take on a leading role in the cancer research agenda and

Proposals

- Scientific journals should publish a complete list of the trial sites and the number of cases/site, in line with the CONSORT guidelines
- Regulatory agencies should require an “ethical clause” that binds the marketing authorization holders to register it in all MICs involved in the trials, to make it available at tiered prices
- Physicians and patients from MICs, hopefully joined by their peers in affluent countries, should lobby for getting a *juxta pretium* (i.e., a morally justifiable “just price”) for the drugs tested in their countries
- The cancer research and development agenda should include LICs, in order to address their specific unmet needs in cancer care