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CLINICAL STUDIES IN MYELODYSPLASIA

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OBJECTIVES

- ▶ What is a clinical trial?
- ▶ What is involved in participating in a clinical trial?
- ▶ How to find the most up-to-date information about clinical trials.

WHAT ARE CLINICAL TRIALS AND WHY DO WE PERFORM THEM?

► What is a clinical trial?

- tests how a drug, medical device, or treatment approach works in people

► Why do we engage in clinical trials?

- Answer scientific questions
- Test new ways to
 - prevent
 - detect
 - diagnose
 - treat
- Treatment trials
 - test new treatment options
- Diagnostic trials
 - test new ways to diagnose a disease
- Screening trials
 - test the best way to detect a disease or health problem.
- Quality of life (supportive care) trials
 - study ways to improve the comfort of people with chronic illness
- Prevention trials
 - look for better ways to prevent disease in people who have never had the disease.



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PHASES OF DRUG CLINICAL TRIALS

▶ Phase I:

- Tests a new drug or treatment in a small group to see if it is safe.

▶ Phase II:

- Expands the study to a larger group of people to find out if it works.

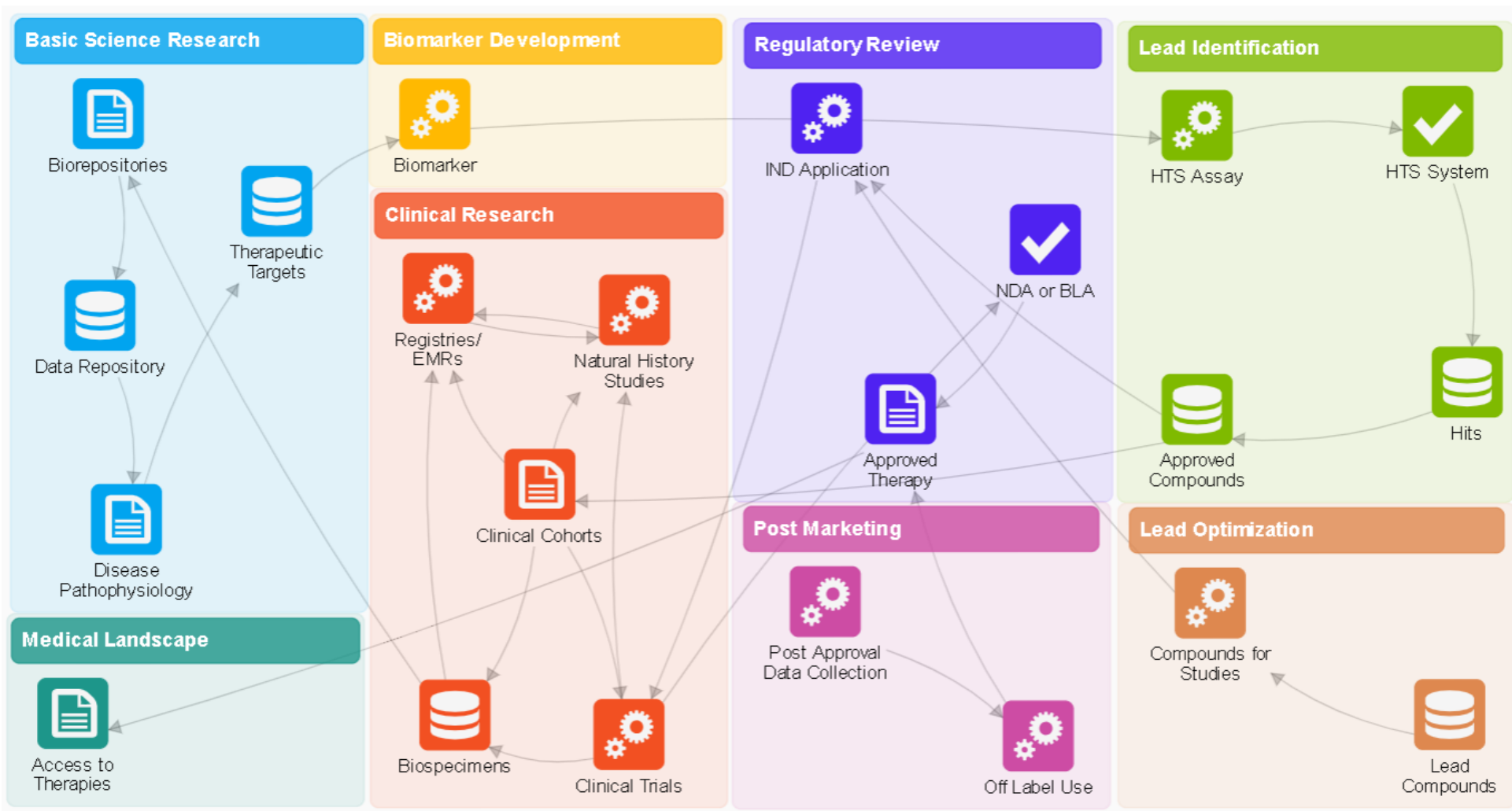
▶ Phase III:

- Expands the study to an even larger group of people to compare it to the standard treatment for the disease.
 - Randomized
 - Placebo controlled
 - Blinded
 - Single vs double blinded

▶ Phase IV

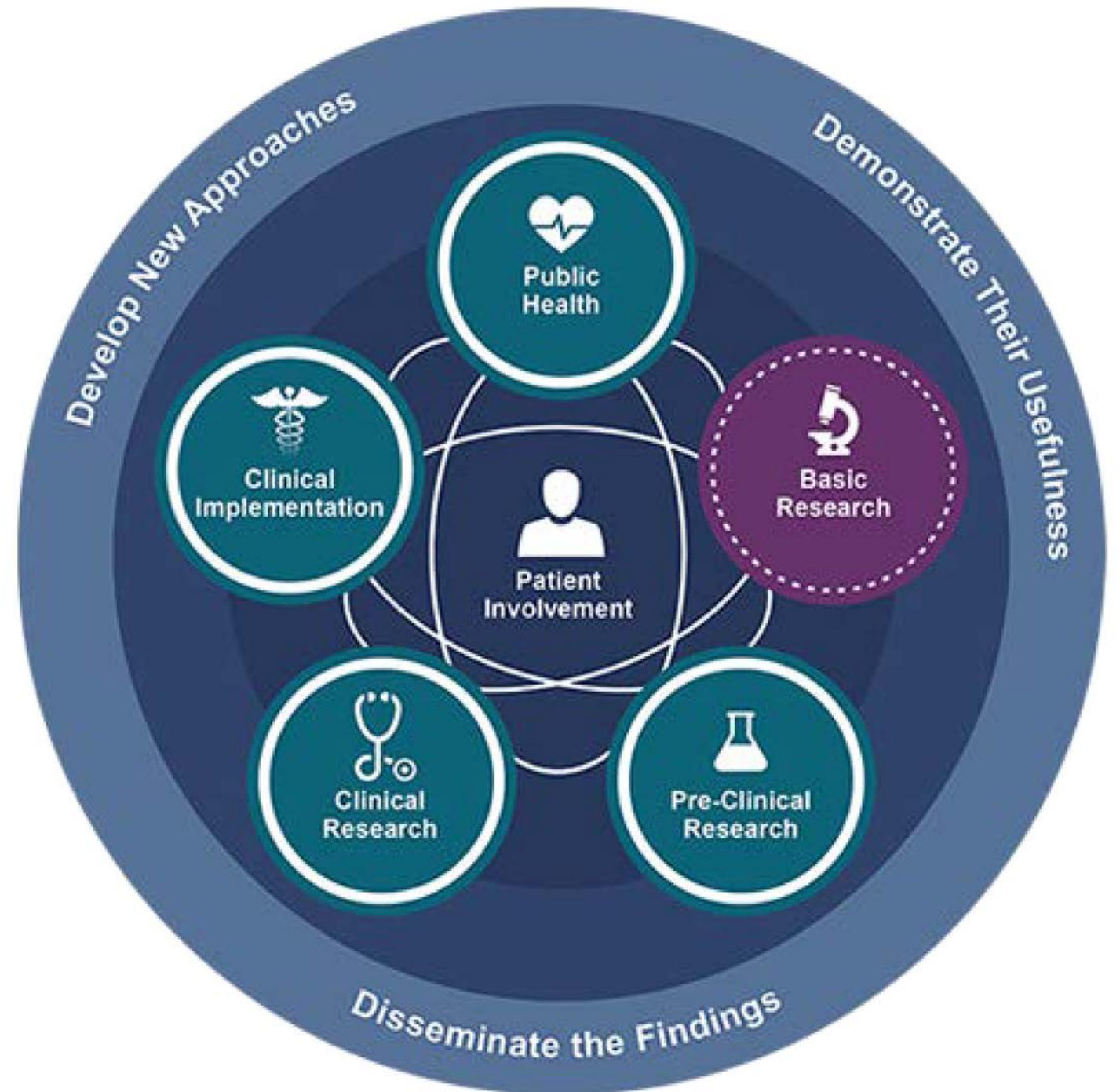
- Takes place after the drug or treatment has been licensed and marketed to find out the long-term impact of the new treatment.

NIH - TRANSLATIONAL ROADMAP



TRANSLATIONAL SCIENCE SPECTRUM

- biological basis of health and disease to interventions that improve the health of individuals and the public
- not linear or unidirectional
- Patient involvement is a critical feature of all stages in translation



RISKS AND BENEFITS

► Benefits

- access to promising new procedures or treatments that are generally not available outside of a clinical trial.
- The new procedure or treatment being studied may be more effective than the current usual approach.
- Trial participants receive high-quality medical care from a research team that includes doctors, nurses, and other health professionals.
- The results of the trial may help other people who need medical care in the future.
- Trial participants are helping scientists learn more about cancer and other medical conditions, which will lead to more advances.

RISKS AND BENEFITS

► Risks

- The new procedure or drug may not be better than what is currently available, or it may have side effects that doctors do not expect or that are worse than the side effects of the current usual approach.
- Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or need to travel farther for those visits.
- Some of the costs of participating in a trial may not be covered by health insurance.

WHAT IS A CLINICAL TRIAL?

- ▶ Clinical trials follow a protocol which is written to meet strict, scientific standards to produce reliable results while at the same time protecting the participants
 - Very specific goals
 - Strict eligibility criteria
 - Specific duration of the study
 - specific information to be gathered is specified
 - Protections against risks to participants and their privacy
 - Informed consent
 - Details about tests, procedures, and treatments
- ▶ Evaluates:
 - Safety & efficacy of new treatments
 - It may compare new treatments to standard treatments
 - It may assess an individual's Quality of life with a type of disease and/or during a specific treatment

MEMBERS OF THE RESEARCH TEAM

1. Lead physician, scientist, or nurse researcher–primary investigator (PI)
2. Other clinicians: physicians, nurse practitioners, or scientists (Sub-Investigators)
3. Statisticians
4. Research staff (nurses, coordinators, Data Managers)

HOW ARE CLINICAL TRIALS MONITORED?

- ▶ **Institutional Review Boards (IRB):** A group of experts from the institution conducting the trial or representing a cooperative group of institutions who review each trial for patient safety and scientific merit. The IRB will continue to monitor the conduct of the trial until it is completed along with the Primary Investigator and the research team.
- ▶ **Data and Safety Monitoring Boards:** An independent committee of physicians, researchers, statisticians, and other experts.

QUESTIONS TO ASK ABOUT PARTICIPATING IN A CLINICAL TRIAL

ABOUT THE STUDY

- What is the purpose of the study?
- Why do researchers think the approach may be effective?
- Who will fund the study?
- Who has reviewed and approved the study?
- How are study results and safety of participants being monitored?
- How long will the study last?
- What will my responsibilities be if I take part?
- Who will tell me about the results of the study and how will I be informed?

QUESTIONS TO ASK ABOUT PARTICIPATING IN A CLINICAL TRIAL

RISKS AND POSSIBLE BENEFITS

- What are my possible short-term benefits?
- What are my possible long-term benefits?
- What are my short-term risks, and side effects?
- What are my long-term risks?
- What other options are available?
- How do the risks and possible benefits of this trial compare with those options?

QUESTIONS TO ASK ABOUT PARTICIPATING IN A CLINICAL TRIAL

PERSONAL

- What kinds of therapies, procedures and/or tests will I have during the trial?
- Will they hurt, and if so, for how long?
- How do the tests in the study compare with those I would have outside of the trial?
- Will I be able to take my regular medications while taking part in the clinical trial?
- Where will I have my medical care?
- Who will be in charge of my care?
- How could being in this study affect my daily life?
- Can I talk to other people in the study?

QUESTIONS TO ASK ABOUT PARTICIPATING IN A CLINICAL TRIAL

COST ISSUES

- Will I have to pay for any part of the trial such as tests or the study drug?
- If so, what will the charges likely be?
- What is my health insurance likely to cover?
- Who can help answer any questions from my insurance company or health plan?
- Will there be any travel or child care costs that I need to consider while I am in the trial?

PROBLEMS WITH CLINICAL TRIALS

- ▶ Currently 96 million have been infected with SARS-CoV2
- ▶ Only 4% have been enrolled in randomized clinical trials
- ▶ Similar to cancer trials - 5-9% enrollment
- ▶ This results in
 - Underrepresented communities (African Americans, rural, and underserved cancer patients)
 - Missed opportunities of (Scientific knowledge and Therapeutic strategies)
- ▶ Non-systematic enrolment of people in less powerful types of studies expose thousands of patients to the potential risks of untested interventions with no reliable way of drawing conclusions about efficacy and safety.
 - Off-label use of medications
 - Hydroxychloroquine
 - Statins
 - Tocilizumab
 - ...

TABLE 1.
Selected Examples of Factors that Impede Participation in Clinical Trials

Barriers to Clinical Trial Participation	Examples
Patient factors or demographics	<ul style="list-style-type: none"> Minority Aging and rural Poor access to care Low socioeconomic status
Patient/community awareness, trust issues and history	<ul style="list-style-type: none"> Mistrust of research/medical system Fear of negative results/effects Historical factors Lack of information on available trials
Physician and researcher barriers	<ul style="list-style-type: none"> Reluctance to refer patients (fear of losing patient) Lack of awareness/knowledge of clinical trials benefits Doctor–patient communications Lack of culturally appropriate researcher training to address patient concerns
Infrastructure, design issues	<ul style="list-style-type: none"> Lack of sufficient number of appropriate clinical trials Disqualification of patients due to eligibility criteria Lack of sufficient infrastructure to support trials in community settings
Perceived or actual cost barriers	<ul style="list-style-type: none"> Patients may be reluctant to participate due to lack of insurance or fears of additional costs Physicians may be reluctant to refer patients due to real and perceived additional costs Oncologists concern: lack of reimbursement for clinical and research costs

From: Baquet CR. The Role of State Legislation and Policy in Addressing Disparities in Clinical Trials. Eliminating Disparities in Clinical Trials (EDICT). http://www.bcm.edu/edict/PDF/State_Legislation.pdf.¹²



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Baquet, C. R., Henderson, K., Commiskey, P. & Morrow, J. N.
Clinical Trials: The Art of Enrollment. *Semin. Oncol. Nurs.* 24,
262-269 (2008).

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- ▶ 86% of clinical trials do not reach their recruitment targets, and approximately 20% close early because of recruitment failure, with important scientific, ethical, financial, and policy implications
- ▶ Even large centres have low recruitment
 - 23% of patients with MDS enrolled in interventional trials at any point in their disease course.
 - narrow eligibility criteria



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Brierley, C. K., Zabor, E. C., Komrokji, R. S., DeZern, A. E., Roboz, G. J., Brunner, A. M., *et al.* Low participation rates and disparities in participation in interventional clinical trials for myelodysplastic syndromes. *Cancer* **126**, 4735–4743 (2020).

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WHAT DOES THE CLINICAL TRIAL LANDSCAPE LOOK LIKE?



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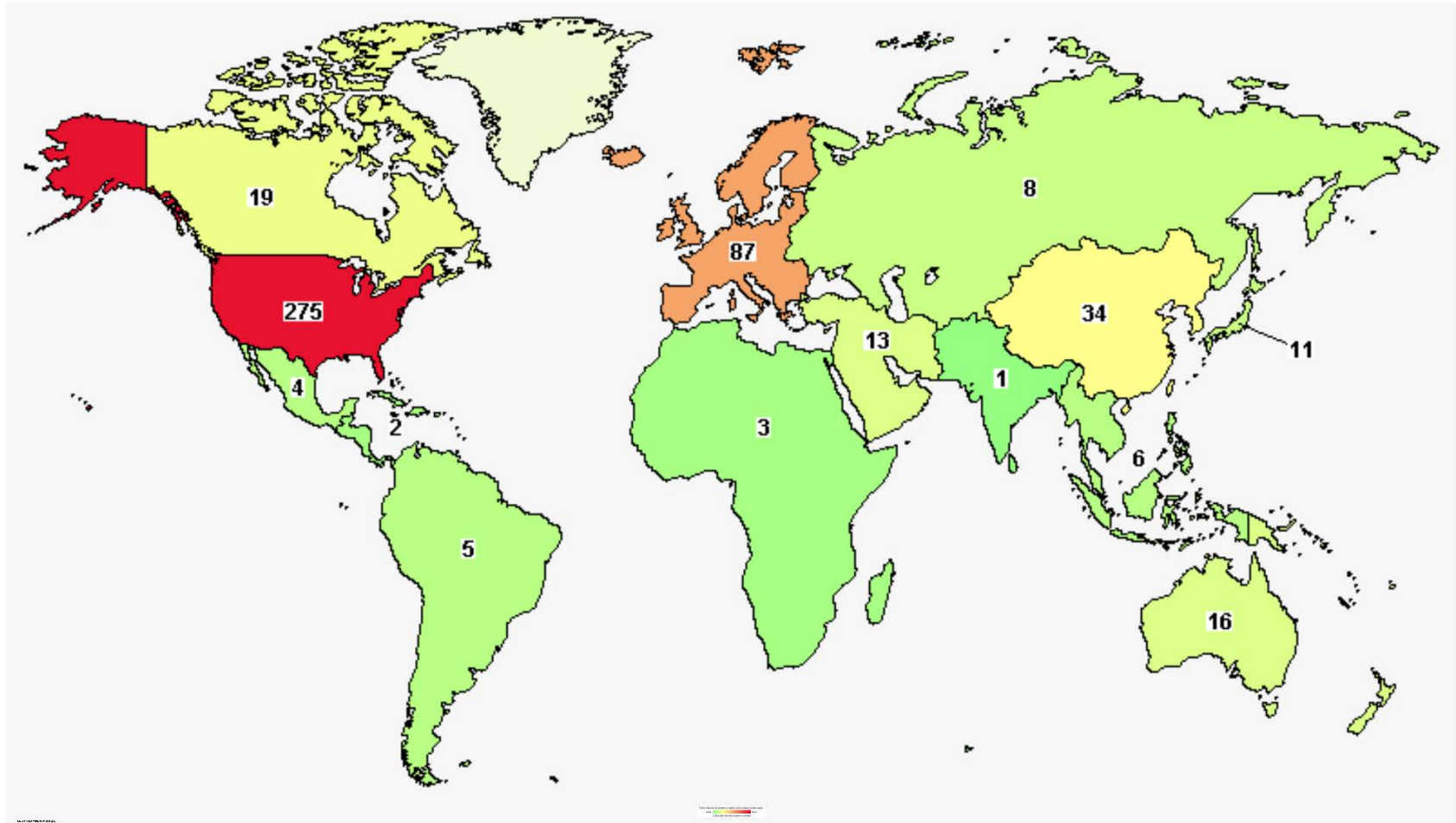
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DISTRIBUTION OF CLINICAL TRIALS FOR MYELODYSPLASTIC SYNDROME AROUND THE WORLD



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HOW DO I FIND THE ONE THAT IS RIGHT FOR ME?

1. TALK TO YOUR DOCTOR
2. UNDERSTAND YOUR DISEASE



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CLASSIFICATION OF MYELOYDYSPLASTIC SYNDROMES

WORLD HEALTH ORGANIZATION CLASSIFICATION OF MYELOYDYSPLASTIC SYNDROMES

Name	Dysplastic lineages	Cytopenias*	Ring sideroblasts as % of marrow erythroid elements	BM and PB blasts	Cytogenetics by conventional karyotype analysis
MDS with single lineage dysplasia	1	1 or 2	<15%/ <5% [†]	BM <5%, PB <1%, no Auer rods	Any, unless fulfills all criteria for MDS with isolated del(5q)
MDS with multilineage dysplasia	2 or 3	1-3	<15%/ <5% [†]	BM <5%, PB <1%, no Auer rods	Any, unless fulfills all criteria for MDS with isolated del(5q)
MDS with ring sideroblasts (MDS-RS)					
MDS-RS with single lineage dysplasia	1	1 or 2	≥15%/≥5% [†]	BM <5%, PB <1%, no Auer rods	Any, unless fulfills all criteria for MDS with isolated del(5q)
MDS-RS with multilineage dysplasia	2 or 3	1-3	≥15%/≥5% [†]	BM <5%, PB <1%, no Auer rods	Any, unless fulfills all criteria for MDS with isolated del(5q)
MDS with isolated del(5q)	1-3	1-2	None or any	BM <5%, PB <1%, no Auer rods	del(5q) alone or with 1 additional abnormality except -7 or del(7q)
MDS with excess blasts (MDS-EB)					
MDS-EB-1	0-3	1-3	None or any	BM 5%-9% or PB 2%-4%, no Auer rods	Any
MDS-EB-2	0-3	1-3	None or any	BM 10%-19% or PB 5%-19% or Auer rods	Any
MDS, unclassifiable (MDS-U)					
MDS-U with 1% blood blasts	1-3	1-3	None or any	BM <5%, PB 1%, [‡] no Auer rods	Any
MDS-U with single lineage dysplasia and pancytopenia	1	3	None or any	BM <5%, PB <1%, no Auer rods	Any
MDS-U based on defining cytogenetic abnormality		0	1-3	≥15% [§]	BM <5%, PB <1%, no Auer rods MDS-defining abnormality
Refractory cytopenia of childhood	1-3	1-3	None	BM <5%, PB <2%	Any

CLINICAL TRIALS IN MYELOYDYSPLSIAS

How are they grouped or divided?

► Research questions being studied

- Treatment by RISK group
 - **LOW**
 - Untreated
 - After failed treatment
 - **HIGH**
 - Initial treatment
 - Relapsed
- Targeted therapy
- Iron overload

INTERNATIONAL PROGNOSTIC SCORING SYSTEM

Prognostic variable	Standard IPSS score				
	0	0.5	1.0	1.5	2.0
Bone marrow blasts	<5%	5%-10%	--	11%-20%	21%-30%
Karyotype*	Good	Intermediate	Poor		
Cytopenias†	0/1	2/3			

*Good = normal, -Y, del 5q, del 20q;

Intermediate = other karyotypic abnormalities;

Poor = complex (≥ 3 abnormalities) or chromosome 7 abnormalities

†Hemoglobin <10 g/dL; ANC <1800/ μ L; platelets <100,000/ μ L



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Greenberg P, et al. *Blood*. 1997;89:2079-2088.

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INTERNATIONAL PROGNOSTIC SCORING SYSTEM

IPSS Score	Risk grouping
0	Low risk
0.5 – 1.0	Intermediate-1 Risk
1.5 – 2.0	Intermediate-2 Risk
≥ 2.5	High risk

TRANSFUSION DEPENDENCE, SURVIVAL AND TRANSFORMATION TO AML BY IPSS SCORE

Parameter	Low	Int-1	Int-2	High
Score	0	0.5-1.0	1.5-2.0	≥2.5
Transfusion dependence	39%	50%	63%	79%
Median AML transformation, Years	9.4	3.3	1.1	0.2
Median survival, Years	5.7	3.5	1.2	0.4



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Greenberg P, et al. Blood 1997;89:2079-2088
Balducci L. Cancer. 2006;106(10):2087-2094

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CLINICAL TRIALS IN MYELOYDYSPLASIAS

- Risk Group

REVISED INTERNATIONAL PROGNOSTIC SCORING SYSTEM

Characteristics	Score values						
	0	0.5	1	1.5	2	3	4
Cytogenetics	Very good	-	Good	-	Intermediate	Poor	Very poor
Blasts BM, %	≤2	-	>2 - <5	-	5-10	>10	-
Hb	≥10	-	8-<10	<8	-	-	-
Platelets	≥100	50-<100	<50	-	-	-	-
Neutrophils	≥0.8	<0.8	-	-	-	-	-

Risk groups

Very low ≤1.5

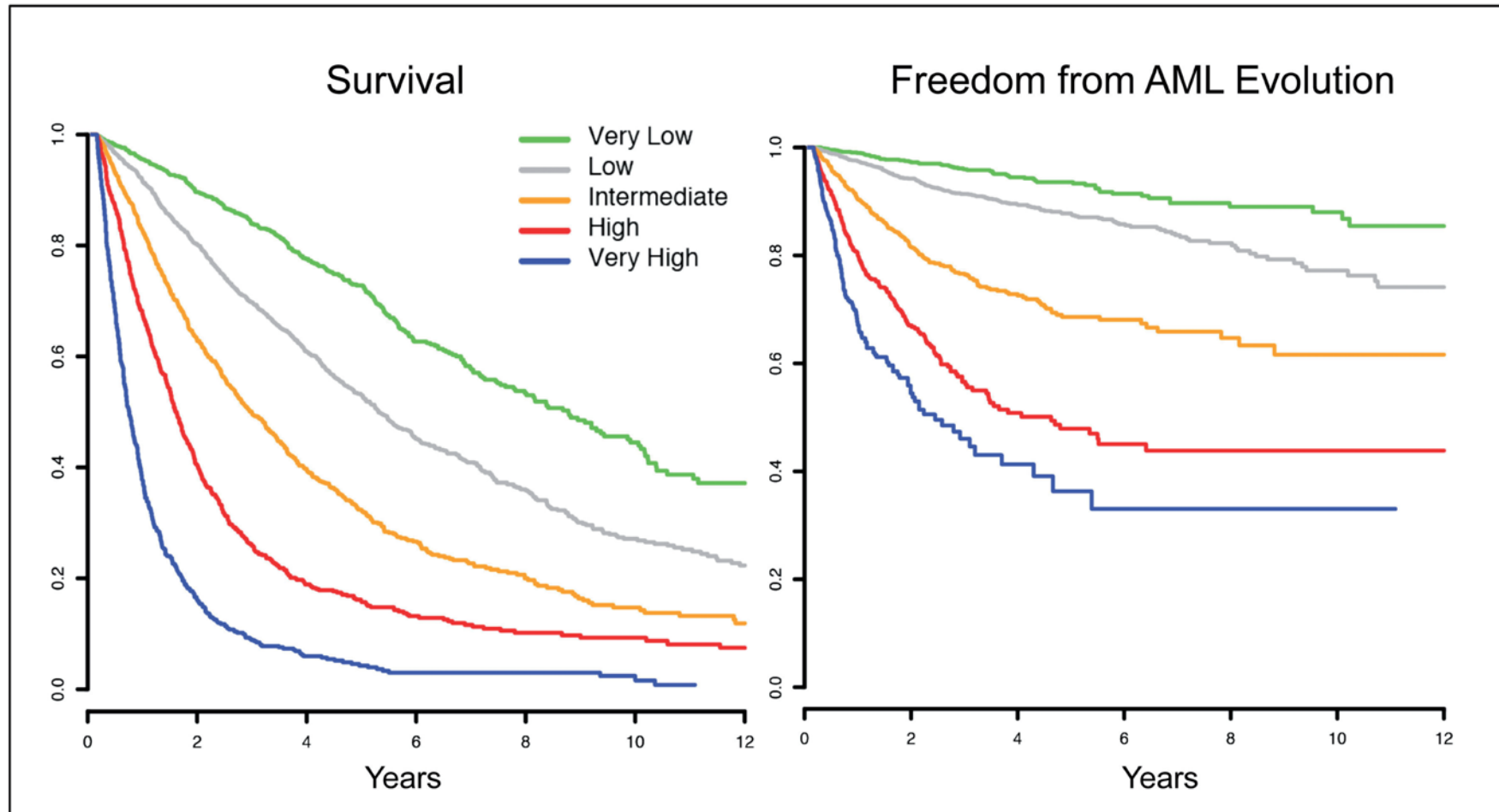
Low >1.5 – 3

Intermediate >3 – 4.5

High >4.5 - 6

Very high >6

REVISED INTERNATIONAL PROGNOSTIC SCORING SYSTEM



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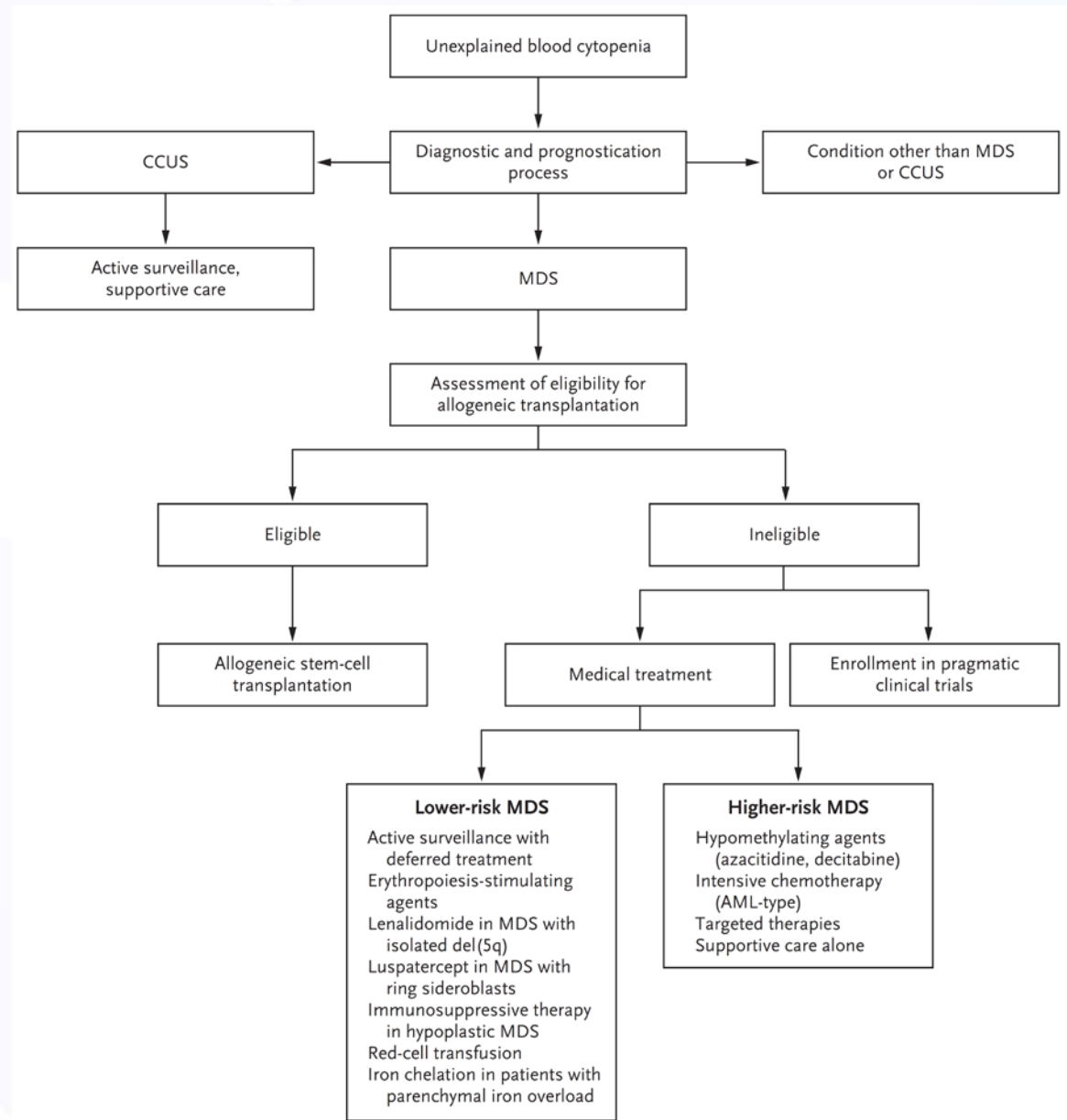
Hellström-Lindberg, E., Tobiasson, M. & Greenberg, P. Myelodysplastic syndromes: Moving towards personalized management. *Haematologica* 105, 1765-1779 (2020).

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APPROACH TO THE TREATMENT OF MDS

Cazzola, M. Myelodysplastic Syndromes. *N. Engl. J. Med.* **383**, 1358–1374 (2020)



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WHERE TO FIND A CLINICAL TRIAL?



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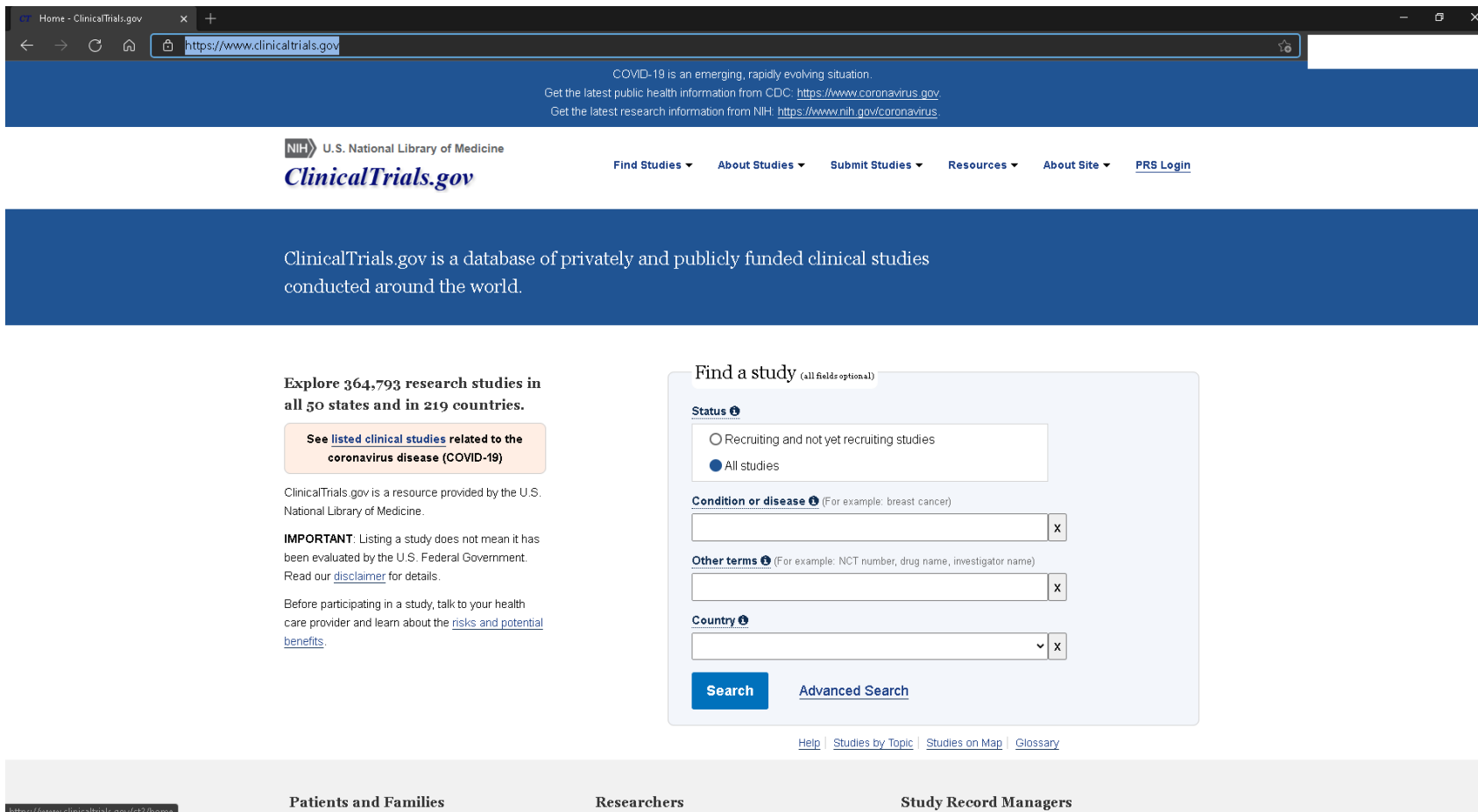
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HTTPS://WWW.CLINICALTRIALS.GOV/



The screenshot shows the ClinicalTrials.gov homepage. At the top, there's a blue banner with COVID-19 information. Below that is the NIH logo and the site name 'ClinicalTrials.gov'. A navigation bar includes links like 'Find Studies', 'About Studies', 'Submit Studies', 'Resources', 'About Site', and 'PRS Login'. A large blue box states: 'ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.' On the left, a section titled 'Explore 364,793 research studies in all 50 states and in 219 countries.' features a button 'See listed clinical studies related to the coronavirus disease (COVID-19)'. Below this is a disclaimer and a link to 'risks and potential benefits'. On the right, a 'Find a study' search box contains filters for 'Status' (Recruiting and not yet recruiting studies, All studies), 'Condition or disease', 'Other terms', and 'Country'. It includes a 'Search' button and a link to 'Advanced Search'. At the bottom, there are links for 'Help', 'Studies by Topic', 'Studies on Map', and 'Glossary'. The footer contains three categories: 'Patients and Families', 'Researchers', and 'Study Record Managers'.

Home - ClinicalTrials.gov

COVID-19 is an emerging, rapidly evolving situation.
Get the latest public health information from CDC: <https://www.cdc.gov/coronavirus>
Get the latest research information from NIH: <https://www.nih.gov/coronavirus>

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾ [PRS Login](#)

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 364,793 research studies in all 50 states and in 219 countries.

See [listed clinical studies](#) related to the coronavirus disease (COVID-19)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Find a study (all fields optional)

Status ⓘ

☐ Recruiting and not yet recruiting studies

☒ All studies

Condition or disease ⓘ (For example: breast cancer)

Other terms ⓘ (For example: NCT number, drug name, investigator name)

Country ⓘ

Search Advanced Search

[Help](#) | [Studies by Topic](#) | [Studies on Map](#) | [Glossary](#)

[https://www.clinicaltrials.gov/ct2/home](#)

Patients and Families Researchers Study Record Managers



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HTTPS://WWW.CANCER.GOV/RESEARCH/INFRASTRUCTURE/CLINICAL-TRIALS

The screenshot shows a web browser window with the URL <https://www.cancer.gov/research/infrastructure/clinical-trials>. The page header features the NIH National Cancer Institute logo and navigation links including "ABOUT CANCER", "CANCER TYPES", "RESEARCH", "GRANTS & TRAINING", "NEWS & EVENTS", and "ABOUT NCI". A search bar is also present. The main content area is titled "NCI's Clinical Trials Programs and Initiatives" and includes a sidebar with links to "CANCER RESEARCH INFRASTRUCTURE", "NCI-Designated Cancer Centers", "Clinical Trials", "NCTN", "NCORP", "Frederick National Laboratory for Cancer Research", and "Bioinformatics, Big Data, and Cancer". The main text explains the importance of clinical trials in cancer research and treatment, mentioning the Food and Drug Administration (FDA) and the need for safety and effectiveness proof. A sidebar on the right contains a "FIND A CLINICAL TRIAL" button and a link to "NCI-supported trials are offered at locations across the United States and Canada." A small image of a child in a hospital setting is also visible.

Research Areas - Clinical Trials

https://www.cancer.gov/research/infrastructure/clinical-trials

NIH NATIONAL CANCER INSTITUTE

Español

1-800-4-CANCER Live Chat Publications Dictionary

ABOUT CANCER CANCER TYPES RESEARCH GRANTS & TRAINING NEWS & EVENTS ABOUT NCI search

Home > Research > Cancer Research Infrastructure

CANCER RESEARCH INFRASTRUCTURE

NCI-Designated Cancer Centers

Clinical Trials

NCTN

NCORP

Frederick National Laboratory for Cancer Research

Bioinformatics, Big Data, and Cancer

NCI's Clinical Trials Programs and Initiatives

ON THIS PAGE

- [Why Clinical Trials Are Critical to Progress against Cancer](#)
- [How New Knowledge about Cancer Is Changing Clinical Trials](#)
- [How NCI Programs Make a Difference](#)
- [How NCI Is Supporting Cutting-Edge Clinical Trials](#)

Why Clinical Trials Are Critical to Progress against Cancer

Clinical trials are essential for moving new methods of preventing, diagnosing, and treating cancer from the laboratory to physicians' offices and other clinical settings and, ultimately, to improve care and quality of life for people with cancer.

In clinical trials, researchers carefully and methodically test drugs, medical devices, screening approaches, behavioral modifications, and other interventions. Trials are used to answer many different clinical questions relevant to all aspects of health care, such as whether a treatment can prevent cancer in people at increased risk, whether a new drug can extend the lives of patients with advanced cancer, or whether specific treatment approaches can improve patients' quality of life. The Food and Drug Administration (FDA) typically requires proof of safety and effectiveness of a new anticancer drug in a large clinical

FIND A CLINICAL TRIAL

NCI-supported trials are offered at locations across the United States and Canada.



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HTTPS://WWW.CANADA.CA/EN/HEALTH-CANADA/SERVICES/DRUGS-HEALTH-PRODUCTS/DRUG-PRODUCTS/HEALTH-CANADA-CLINICAL-TRIALS-DATABASE.HTML

The screenshot shows a web browser window with the URL <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/health-canada-clinical-trials-database.html>. The page header includes the Government of Canada logo and a search bar. A breadcrumb trail reads: Canada.ca > Departments and agencies > Health Canada > Drugs and health products > Drug products. A left-hand menu lists various topics, with 'Health Canada's Clinical Trials Database' highlighted. The main content area is titled 'Health Canada's Clinical Trials Database' and contains the following text:

Health Canada, through its Clinical Trials Database, is providing to the public a listing of specific information relating to phase I, II and III clinical trials in patients. The database is managed by Health Canada and provides a source of information about Canadian clinical trials involving human pharmaceutical and biological drugs.

Patients can access the database to determine if a clinical trial has met the regulatory requirements. The database may also assist Canadians in finding clinical trials that might be relevant to their medical condition.

The Clinical Trials Database is not a registry, and therefore, it does not contain comprehensive information about each clinical trial. To maximise use of the database and available information, users are advised to link to external resources, including publicly available registries, to obtain further information such as trial objectives and patient eligibility. Note however that not all clinical trials are necessarily registered and thus found in these registries. Health Canada continues to encourage sponsors to register their clinical trials in publically accessible registries such as [ClinicalTrials.gov](https://clinicaltrials.gov) and [ISRCTN](https://isrctn.com). A Canadian-based registry for cancer trials is also available at [Canadian Cancer Trials](https://canadiancancertrials.ca). Additionally, the search portal provided by the [World Health Organization \(WHO\)](https://www.who.int) can be used to access a central database that contains information about trials registered in several international registries.

A callout box on the right side of the main text contains the link: [Access the Clinical Trials Database](#).



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HTTPS://TRIAL-FINDER.CTONTARIO.CA/

The screenshot shows the Clinical Trials Ontario Trial Finder website. The browser address bar displays <https://trial-finder.ctontario.ca>. The website header includes the Clinical Trials Ontario logo and navigation links: WHO WE ARE, NEWS & EVENTS, CTO PROGRAMS, INDUSTRY & INSTITUTIONS, and PATIENTS & PUBLIC. A search bar is located in the top right corner.

On the left side, there is a sidebar with search filters, each with a green checkmark indicating it is active:

- Condition: myelodysplastic syndrome
- Location
- Study Phase
- Your Demographics
- Keywords
- Subscribe

Below the filters are two buttons: "Search" and "Clear".

The main content area displays the results of the search. At the top, it states "Number of results found: 12" with social media sharing icons. The results are listed in three numbered items:

- 1) A Dose-finding Study of CC-90009 in Subjects With Relapsed or Refractory Acute Myeloid Leukemia or Relapsed or Refractory Higher-risk Myelodysplastic Syndromes**
 - Disease / Condition:** Leukemia, Myeloid, Acute Myelodysplastic Syndromes
 - Study Phase:** Phase 1
 - Nearest Centres:** Princess Margaret Hospital, University Health Network
 - Recruitment Status:** Recruiting
 - Trial Start Date:** 2016-11-14
 - Date Posted:** 2016-07-28
 - Info Last Updated:** 2021-01-13
- 2) A Study Evaluating Venetoclax in Combination With Azacitidine in Participants With Treatment-Naïve Higher-Risk Myelodysplastic Syndromes (MDS)**
 - Disease / Condition:** Myelodysplastic Syndromes (MDS)
 - Study Phase:** Phase 1
 - Nearest Centres:** Juravinski Cancer Clinic /ID# 152947
 - Recruitment Status:** Recruiting
 - Trial Start Date:** 2017-01-12
 - Date Posted:** 2016-10-24
 - Info Last Updated:** 2021-01-06
- 3) A Phase 2 Study of CPI-0610 With and Without Ruxolitinib in Patients With Myelofibrosis**
 - Disease / Condition:** Myelofibrosis, Leukemia, Myelocytic, Acute Myelodysplastic/Myeloproliferative Neoplasm, Myelodysplastic Syndrome (MDS)
 - Study Phase:** Phase 1/Phase 2
 - Nearest Centres:** Juravinski Cancer Centre, Princess Margaret Hospital, Princess Margaret Cancer Centre
 - Recruitment Status:** Recruiting
 - Trial Start Date:** 2014-06-01
 - Date Posted:** 2014-06-01
 - Info Last Updated:** 2021-01-06



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[HTTPS://WWW.CTG.QUEENSU.CA/PUBLIC/HEMATOLOGIC/HEMATOLOGIC-DISEASE-SITE](https://www.ctg.queensu.ca/public/hematologic/hematologic-disease-site)

Canadian Cancer Trials Group

Groupe canadien des essais sur le cancer

A national academic led research group conducting cancer clinical trials.

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For the latest COVID-19 (Coronavirus) information: [CCTG public updates](#) | [CCTG member information](#)

Hematologic Disease Site

Hematologic

Select Disease Site

ID Sort ++	Study Title	Status Sort ++
AL6 (CCTG AL6)	A Measurable Residual Disease (MRD) Driven, Phase II Study of Venetoclax Plus Chemotherapy for Newly Diagnosed Younger Patients with AML + Read More	Planned
CL4	Randomized Phase II Evaluation of Lower-dose (3-2-1 strategy) vs Full Dose of Ibrutinib for the Treatment of Relapsed or Refractory Chronic Lymphocytic Leukemia + Read More	Planned
CLC3 (SWOG S1925)	Randomized Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study + Read More	Planned
HD10 (NCRI (UK))	A Randomized Phase III Trial with a PET Response Adapted Design Comparing ABVD +/- ISRT with A2VD +/- ISRT in Patients with Previously Treated Stage IA/IIA Hodgkin Lymphoma (RADAR) + Read More	Planned

Partnerships
500+ trials in 40+ countries

IND Program
36+ years experience in 205+ drug trials

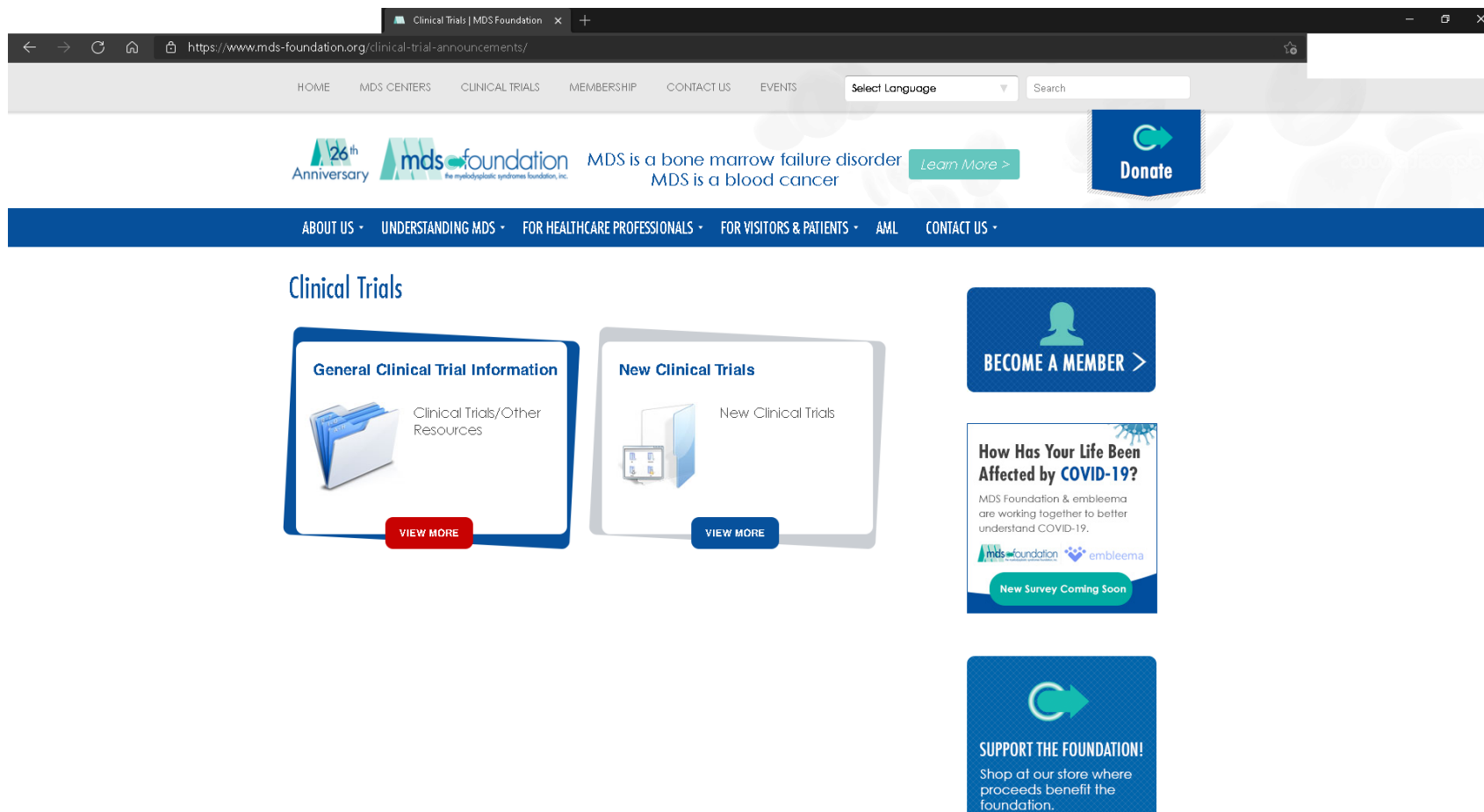
Tissue Bank
300,000+ samples from 120+ trials

Network
2100+ investigators at 85+ sites

Become a
CCTG Investigator

Living with cancer through COVID-19

HTTPS://WWW.MDS-FOUNDATION.ORG/CLINICAL-TRIAL-ANNOUNCEMENTS/



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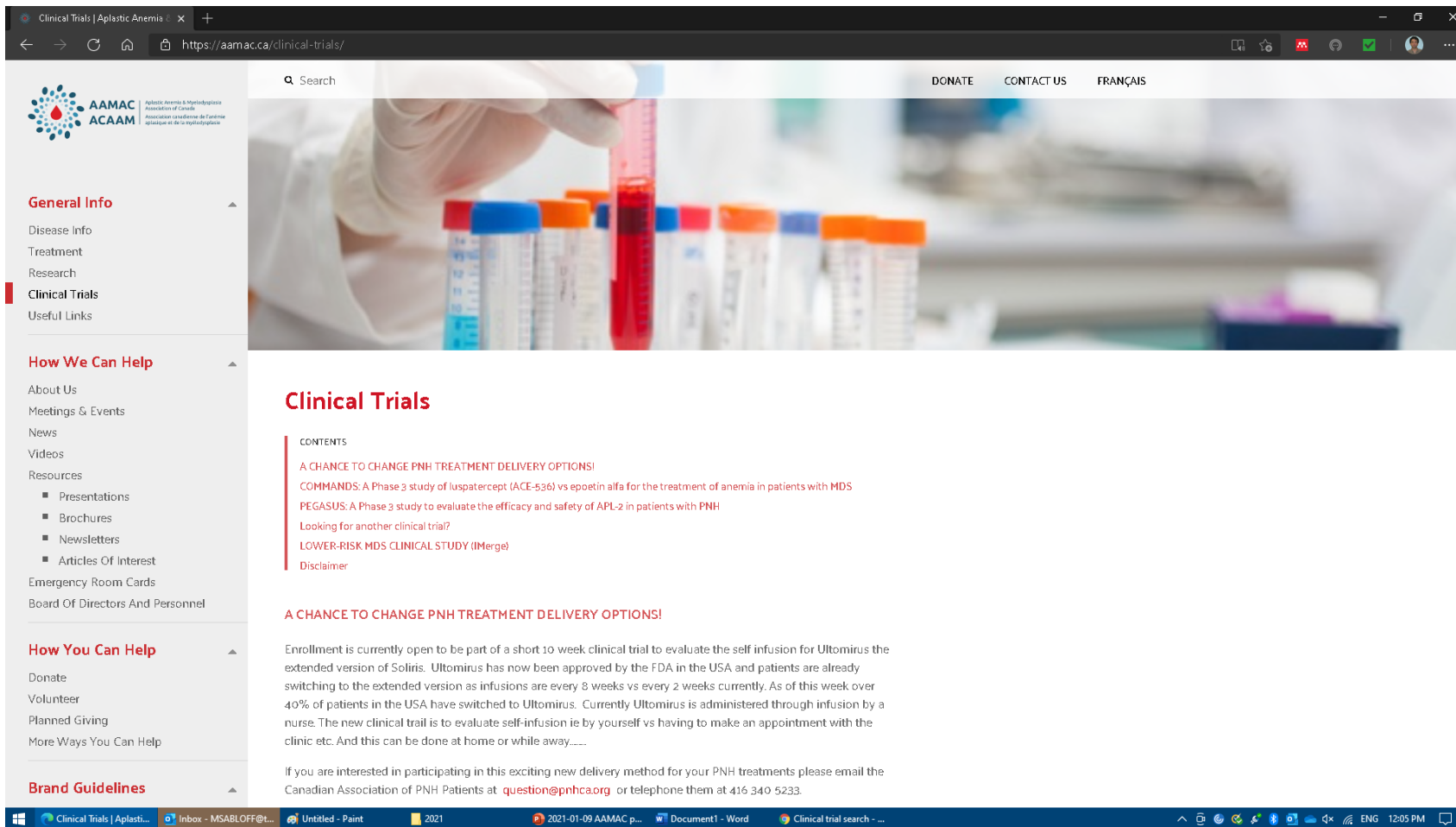
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HTTPS://AAMAC.CA/CLINICAL-TRIALS/



The screenshot shows a web browser window displaying the AAMAC Clinical Trials website. The browser's address bar shows the URL <https://aamac.ca/clinical-trials/>. The website has a dark header with a search bar, navigation links for "DONATE", "CONTACT US", and "FRANÇAIS", and a large background image of a hand holding a test tube. A left sidebar contains a menu with categories: "General Info" (Disease Info, Treatment, Research), "Clinical Trials" (Useful Links), "How We Can Help" (About Us, Meetings & Events, News, Videos, Resources, Emergency Room Cards, Board Of Directors And Personnel), "How You Can Help" (Donate, Volunteer, Planned Giving, More Ways You Can Help), and "Brand Guidelines". The main content area is titled "Clinical Trials" and includes a "CONTENTS" section with links to "A CHANCE TO CHANGE PNH TREATMENT DELIVERY OPTIONS!", "COMMANDS: A Phase 3 study of lusparcept (ACE-536) vs epoetin alfa for the treatment of anemia in patients with MDS", "PEGASUS: A Phase 3 study to evaluate the efficacy and safety of APL-2 in patients with PNH", "Looking for another clinical trial?", "LOWER-RISK MDS CLINICAL STUDY (IMerge)", and "Disclaimer". Below this, the "A CHANCE TO CHANGE PNH TREATMENT DELIVERY OPTIONS!" section provides details about a clinical trial for Ultomiris, including enrollment status and contact information. The Windows taskbar at the bottom shows several open applications and the system clock at 12:05 PM on 2021-01-09.

Clinical Trials | Aplastic Anemia

[https://aamac.ca/clinical-trials/](#)

AAMAC
ACAAM
Aplastic Anemia & Myelodysplasia
Association of Canada
Association canadienne de l'anémie
aplastique et de la myélodysplasie

General Info

- Disease Info
- Treatment
- Research
- Clinical Trials**
- Useful Links

How We Can Help

- About Us
- Meetings & Events
- News
- Videos
- Resources
 - Presentations
 - Brochures
 - Newsletters
 - Articles Of Interest
- Emergency Room Cards
- Board Of Directors And Personnel

How You Can Help

- Donate
- Volunteer
- Planned Giving
- More Ways You Can Help

Brand Guidelines

Clinical Trials

CONTENTS

- [A CHANCE TO CHANGE PNH TREATMENT DELIVERY OPTIONS!](#)
- [COMMANDS: A Phase 3 study of lusparcept \(ACE-536\) vs epoetin alfa for the treatment of anemia in patients with MDS](#)
- [PEGASUS: A Phase 3 study to evaluate the efficacy and safety of APL-2 in patients with PNH](#)
- [Looking for another clinical trial?](#)
- [LOWER-RISK MDS CLINICAL STUDY \(IMerge\)](#)
- [Disclaimer](#)

A CHANCE TO CHANGE PNH TREATMENT DELIVERY OPTIONS!

Enrollment is currently open to be part of a short 10 week clinical trial to evaluate the self infusion for Ultomiris the extended version of Soliris. Ultomiris has now been approved by the FDA in the USA and patients are already switching to the extended version as infusions are every 8 weeks vs every 2 weeks currently. As of this week over 40% of patients in the USA have switched to Ultomiris. Currently Ultomiris is administered through infusion by a nurse. The new clinical trail is to evaluate self-infusion is by yourself vs having to make an appointment with the clinic etc. And this can be done at home or while away....

If you are interested in participating in this exciting new delivery method for your PNH treatments please email the Canadian Association of PNH Patients at question@pnhca.org or telephone them at 416 340 5233.



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Looking for another clinical trial?

AAMAC works with partners to provide ways to participate in clinical trials near you. There are several ways to find clinical trials, including a quick search function provided by Antidote.

Match to clinical trials in 60 seconds

- Know your options
- Access the latest treatments in development
- Advance medical research, for good

START

Powered by **antidote**  



Antidote delivers clear, unbiased information about clinical trial options. They aim to match patients to the best trial, regardless of the sponsor. Find their privacy policy [here](#).



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LOCAL TRIALS - OTTAWA

▶ Lower risk

- COMMANDS

- Luspatercept (Ace-536) Versus Epoetin Alfa For The Treatment Of Anemia Due To Ipss-r Very Low, Low Or Intermediate Risk Myelodysplastic Syndromes (Mds) In Esa Naïve Subject Who Require Red Blood Cell Transfusions

- IMERGE

- Imetelstat (GRN163L) in Transfusion-Dependent Subjects with IPSS Low or Intermediate-1 Risk MDS that is Relapsed/Refractory to erythropoietic stimulating agent Treatment

▶ Higher risk

▶ Canadian Myelodysplastic Syndromes Priority Setting Partnership



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LOCAL TRIALS – TORONTO [[HTTPS://PM.CTRALFINDER.COM/LIST-VIEW](https://pm.ctralfinder.com/list-view)]

- ▶ A phase I/II study to investigate the safety and clinical activity of GSK3326595 and other agents in subjects with myelodysplastic syndrome and acute myeloid leukaemia
- ▶ A phase 3b open-label, single arm, rollover study to evaluate long-term safety in subjects who have participated in other luspatercept (ACE-536) clinical trials (NCT04064060)
- ▶ An open-label, dose escalation, safety and pharmacokinetic study of CFI-400945 fumarate administered orally in patients with relapsed or refractory acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS)
- ▶ Phase Ib/II study of IDH2 inhibitor enasidenib in combination with BCL2 inhibitor venetoclax in patients with IDH2-mutated myeloid malignancies
- ▶ A phase 1/2, multicenter, open-label study of FT-2102 as a single agent and in combination with azacitidine in patients with acute myeloid leukemia or myelodysplastic syndrome with an IDH1 mutation



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OTHER TRIALS

- ▶ **Safety And Efficacy Study Of Venetoclax Tablet With Intravenous or Subcutaneous Azacitidine to Assess Change in Complete Remission and Overall Survival In Adult Participants With Newly Diagnosed Higher-Risk Myelodysplastic Syndrome**
- ▶ **A Phase III Study Evaluating The Efficacy And Safety Of Crovalimab Versus Eculizumab In Participants With Paroxysmal Nocturnal Hemoglobinuria (PNH) Not Previously Treated With Complement Inhibitors.**
- ▶ **Magrolimab + Azacitidine Versus Azacitidine + Placebo in Untreated Participants With Myelodysplastic Syndrome (MDS)**
- ▶ **Comparing Two Diets in Patients Undergoing HSCT or Remission Induction Chemo for Acute Leukemia and MDS (UF-BMT-LDND-101)**
- ▶ **Study of Efficacy and Safety of MBG453 in Combination With Azacitidine in Subjects With Intermediate, High or Very High Risk Myelodysplastic Syndrome (MDS) as Per IPSS-R, or Chronic Myelomonocytic Leukemia-2 (CMML-2)**



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