

IMPACT-AML
EU collaborative STREAM
for leukemia patients

Part of Mission Cancer Diagnosis & Treatment Cluster



IMPACT-AML

IMPACT-AML Master Framework and Pragmatic Clinical Trial for Relapsed or Refractory Acute Myeloid Leukemia is a European project that aims to build a pioneering research framework for Relapsed or Refractory Acute Myeloid Leukemia, unifying patients, clinicians, and researchers across Europe and beyond. At its core, STREAM enables real-world evidence integration and supports R/R AML pragmatic clinical trials, laying the foundation for future patient-centric treatments and the advancement of collaborative innovation in AML care.

Our mission

The IMPACT-AML consortium is committed to transforming the treatment landscape of R/R AML by developing an inclusive research framework that ensures no patient is left behind. Through data harmonization, biobanking standardization, and the first cutting-edge clinical trials, the partners aim to generate robust scientific evidence that will drive better and standardised therapies across the EU, ensuring equitable access to care for all AML patients.



Numbers

20,000

people suffering from relapsed/refractory AML in Europe every year less than 20%

is the **survival rate** after chemotherapy reinduction



no **standard of care** exists for
R/R AML patients

Objectives of the project

- Design an inclusive framework for R/R AML (i.e. STREAM)
- Design and perform a Randomized Pragmatic Clinical Trial (RPCT) comparing low-intensity and standard chemotherapy rescue
- Increase patient engagement in clinical trial, by including, patients' and caregivers' perspectives in the RPCT design and evaluation and evaluation
- Develop Standard Operating Procedures (SOPs) for local biobanking, including samples for measurable residual disease (MRD) quantification to enhance biological knowledge in R/R AML
- Pave the way for new clinical trials on pediatric and orphans cohorts

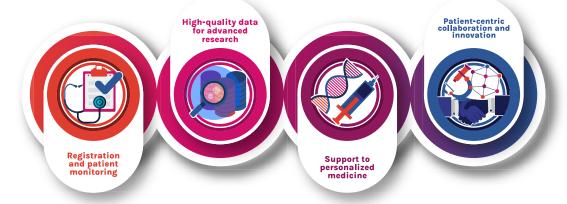
What is R/R AML?

Relapsed or Refractory Acute Myeloid Leukemia (R/R AML) refers to a form of AML where the disease either returns after successful initial treatment (relapsed) or does not respond to standard therapies (refractory).

It is one of the **most challenging haematological cancers to treat,** with a 5-year overall survival (rate below 20% in adults and 30–35% in children).

What is STREAM?

STREAM is an innovative patient registry designed to transform the treatment landscape for Relapsed or Refractory Acute Myeloid Leukemia (R/R AML). By integrating patients across Europe, STREAM will ensure an inclusive, real-world registry that collects clinical, genetic, and treatment data. STREAM's dynamic design accommodates neglected populations, enabling comprehensive monitoring of outcomes while setting the foundation for ground-breaking clinical research.



The IMPACT-AML Randomized Pragmatic Clinical Trial

The IMPACT-AML RPCT is a phase III, randomized, pragmatic, multicenter clinical trial designed to compare low-intensity versus high-intensity treatments in adult patients with R/R AML who have received one or two prior lines of therapy. Participants must be clinically eligible for either approach, reflecting real-world decision-making scenarios. The primary objective is to assess event-free survival (EFS) as a measure of clinical effectiveness, with secondary endpoints including overall survival (OS), response rates, safety and patient-reported outcomes.



The IMPACT-AML project brings together 17 partners from across Europe, and this international collaboration is key to combining diverse expertise and driving progress in the fight against Relapsed/Refractory Acute Myeloid Leukemia.

Coordination



EMILIA-ROMAGNA

Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori" Istituto di Ricovero e Cura a Carattere Scientifico





Partners































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