



# **IMPACT-AML EU collaborative STREAM for leukemia patients**

Part of Mission Cancer  
Diagnosis & Treatment Cluster



Funded by  
the European Union

# 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



**people suffering from**  
relapsed/refractory  
AML in Europe every year



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.

High-quality data  
for advanced  
research



Registration  
and patient  
monitoring



Support to  
personalized  
medicine



Patient-centric  
collaboration and  
innovation



# 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



**SERVIZIO SANITARIO REGIONALE  
EMILIA-ROMAGNA**

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

ISTITUT  
ROMAGNOLO  
PER LO STUDIO  
DEI TUMORI  
DINO AMADORI



ALMA MATER STUDIORUM  
UNIVERSITÀ DI BOLOGNA

## Partners



**TIMELEX**



## External Supporters



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