

Statistics Department Internship Day Sapienza University of Rome

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18th October 2024



fondazione GIMEMA onlus
per la promozione e lo sviluppo della ricerca scientifica
sulle malattie ematologiche. **FRANCO MANDELLI**



GIMEMA Foundation

- GIMEMA Foundation is a recognised institution that coordinates a national network involving **almost all Italian haematological centers**. It also manages a broad range of international collaborations.
- The GIMEMA Foundation was established in 1982 based on a suggestion by Professor Franco Mandelli
- **GIMEMA research** aims to improve the standard of care and quality of life for patients with haematologica diseases.



GIMEMA Foundation conducts and coordinates independent clinical studies in the field of haematological diseases of adults.

42

YEARS
OF RESEARCH

54

CLINICAL TRIALS
DURING 2023

40

PUBLICATIONS
IN 2023

140⁺

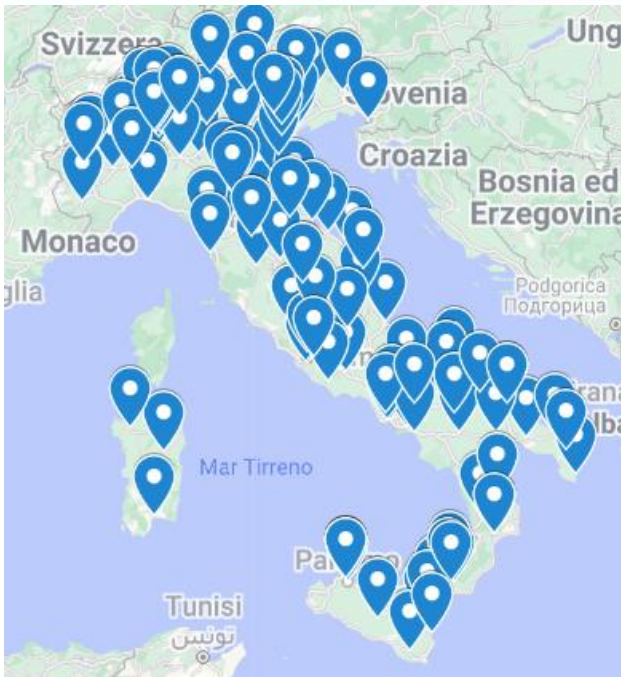
CENTRES IN
ITALY

60⁺

LABS AROUND
THE COUNTRY

9

WORKING
PARTIES



Through a network organization, which also boasts a complex **centralized diagnostic tasks**, all Italian centers belonging to GIMEMA are able to provide patients with the **same diagnostic and therapeutic procedures** regardless of their place of care.



Working parties

The Working Parties (WP) are at the core of GIMEMA's scientific operation. They are **work teams** focusing on specific topics in the field of haematology.

The WPs are scientifically autonomous and operate in full compliance with the procedures that the Foundation adopts in conducting its **clinical trials**.

There are **9 operational Working Parties**, some geared towards specific types of pathologies while others adopt a more cross-sectional approach to address a variety of topics and pathologies.

Workies Parties GIMEMA

Acute Leukaemia and
Myelodysplastic Syndrome WP

Chronic Myeloproliferative Neoplasm
WP

Chronic Lymphoproliferative
Syndromes WP

Thrombocytopenia and Anaemia WP

Immunotherapy WP

Haemostasis and Thrombosis WP

Quality of life WP

Infection WP

Multiple Myeloma WP



Headquarter



Data Center

- The Rome-based Data Center is the operational hub that coordinates all of the Foundation's research activities.
- It is a structure of excellence, certified at European level and internationally acknowledged for the management of Clinical Trials.
- **More than 40 people, specialized in many different areas, work at the Data Centers.** They include doctors, biologists, project managers, IT experts, data managers, statisticians and legal personnel.

Main Activities

- Design and organisation of Clinical Trials: from concept to protocol drafting, management of regulatory affairs and communications with Ethics Committees and competent authorities.
- Clinical trial conduct, coordination of participating centers, data collection management.
- Pharmacovigilance, statistical analysis and publication of reports and scientific papers.
- Organization of training courses and scientific dissemination activities



The Role of Biostatistics in GIMEMA Foundation Activities

Study Design:

- Biostatistics aids in structuring clinical trials to ensure scientifically sound methods and robust outcomes.

Data Management and Analysis:

- Advanced biostatistical techniques are used to handle large datasets, ensuring accurate data analysis to support clinical decisions.

Outcome Prediction Models:

- Biostatistics enables the creation of predictive models for patient outcomes, improving personalized treatment strategies.

Support for Innovation:

- Biostatisticians are essential in integrating AI and machine learning for innovative solutions in trial analysis and patient care



Variation in the Duration of Survival of Patients with Acute Leukemia

By BRIAN MACMAHON AND DONALD FORMAN

RESULTS

Variation by Cell Type

Percentage survival for various periods after diagnosis is shown for the total 623 patients in figure 1. Almost half the patients died before the end of the first month after diagnosis, and half again of the survivors to the first month died

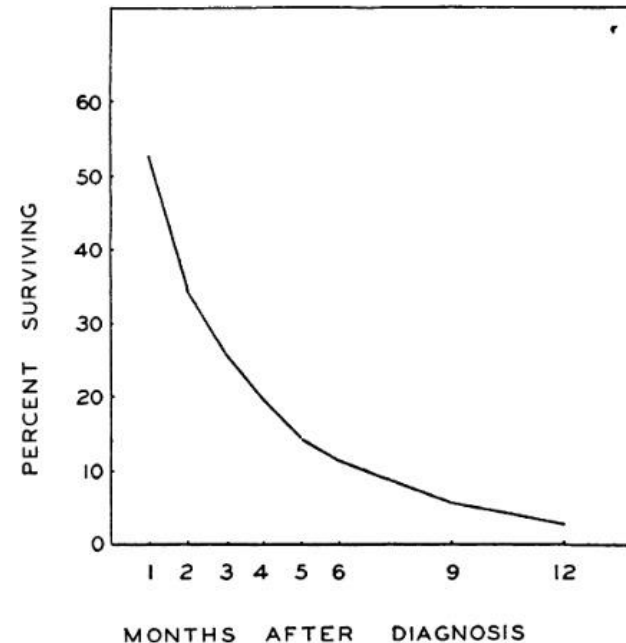
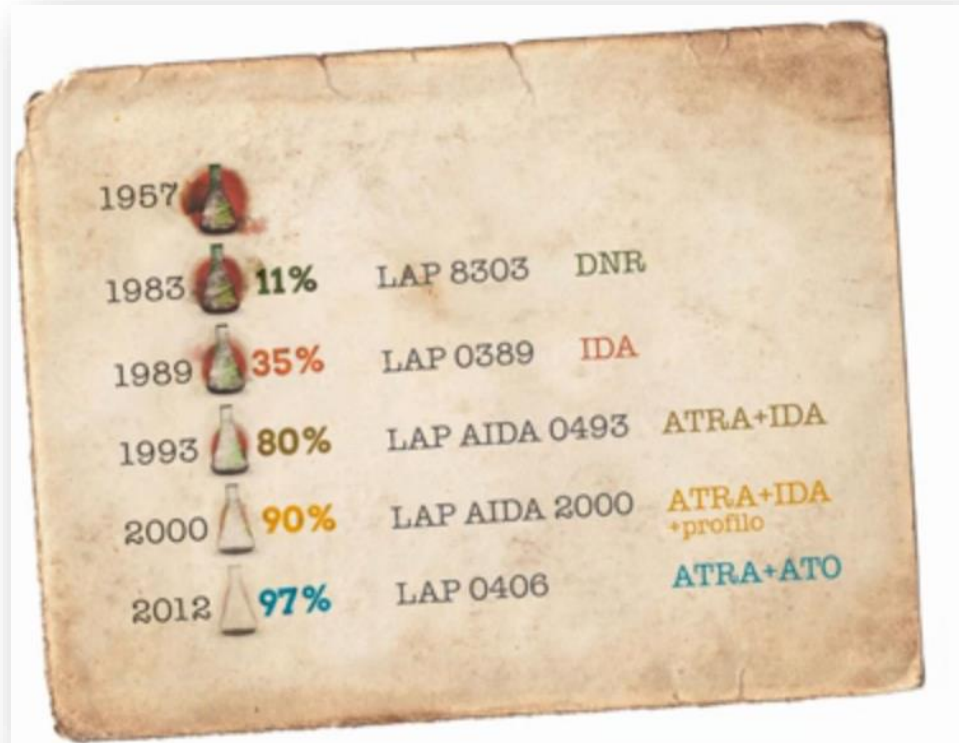


FIG. 1.—Percentage of patients with acute leukemia surviving for various periods after diagnosis, Brooklyn, 1943-52.

GIMEMA APL history



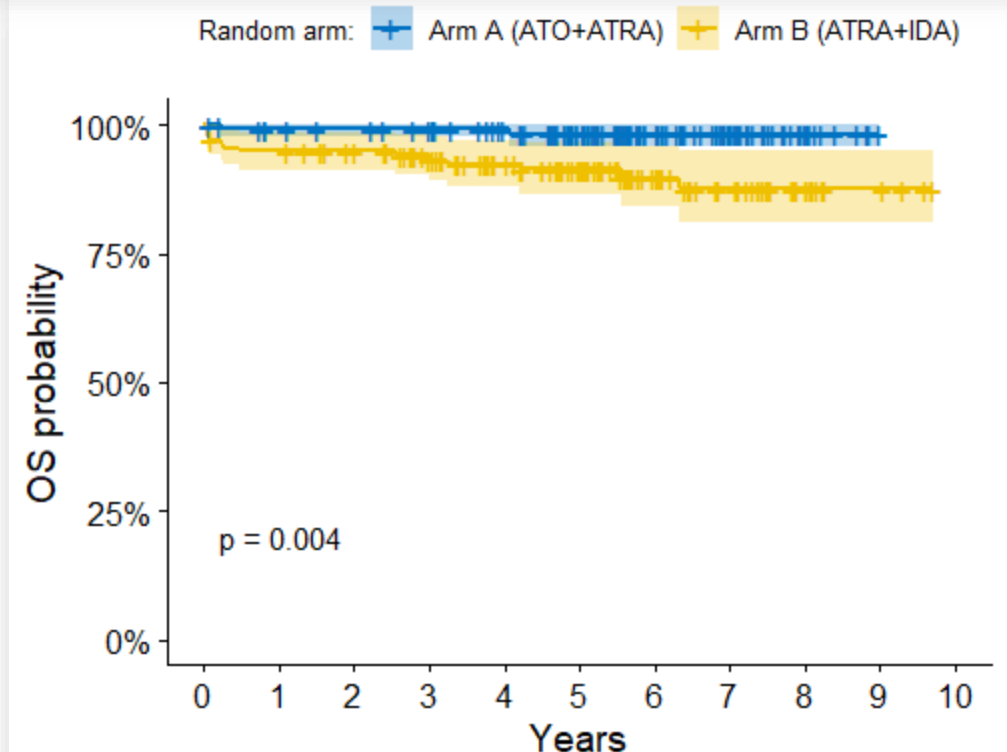
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Retinoic Acid and Arsenic Trioxide for Acute Promyelocytic Leukemia





Durata 3:30