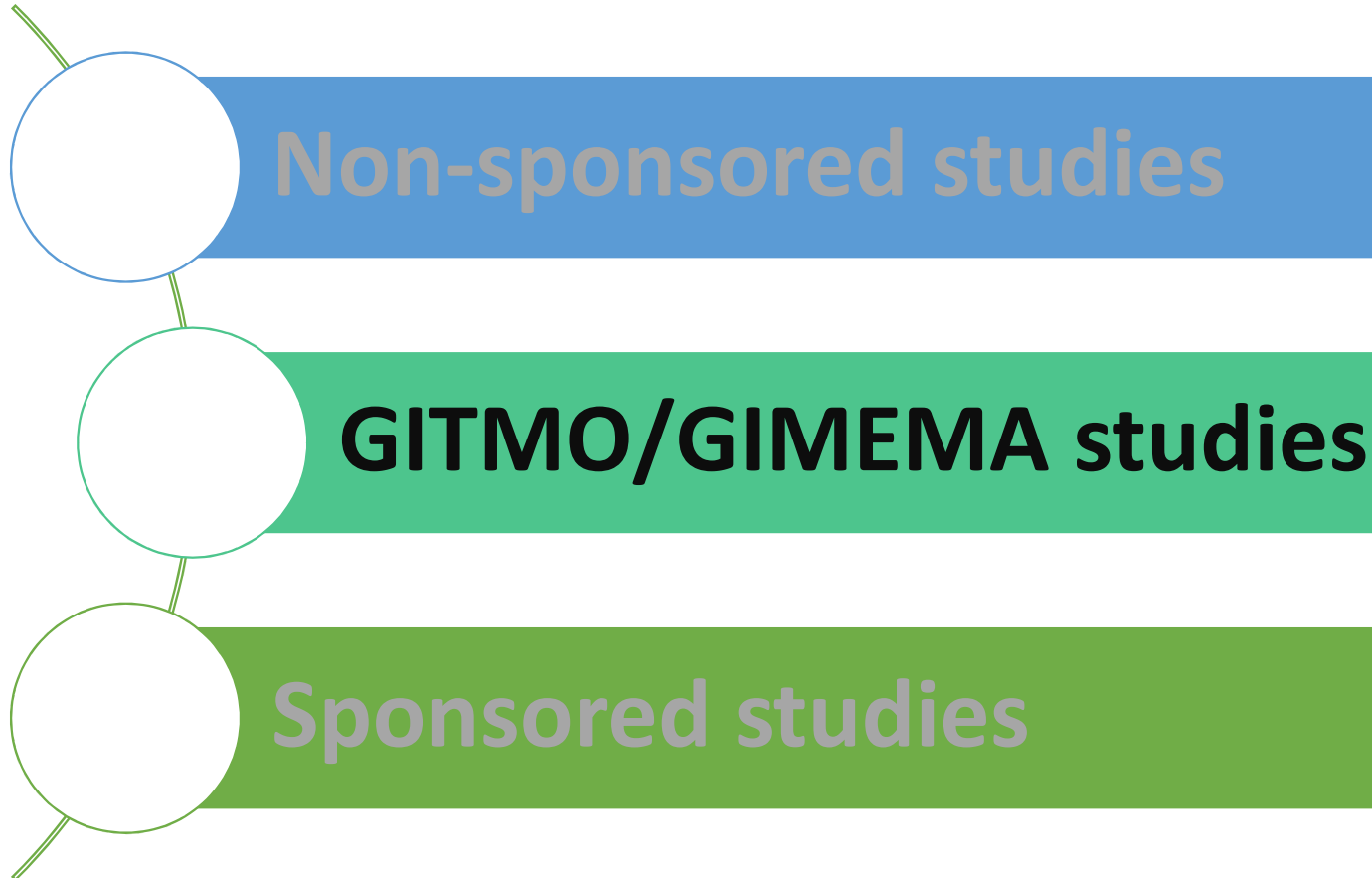


# Update Ongoing Trials BS BMT-Unit



## Ongoing GITMO/GIMEMA studies (2020)

Studies	Submitted EC	EC approval	Enrolled patients	Published abstract	Published full paper
DLI in Acute Leukemia: GITMO-DLI	Yes	21/Nov/2017	4	No	Yes
Donor-specific anti-HLA abs: GITMO AIBT DSAs	Yes	20-Feb-2018			
Elastometry in VOD: ELASTOVOD	Yes	9/Oct/2018	22	No	No
cGVHD according NIH criteria: GITMO-GVCrOSY	Yes	15/Jun/2017	6	No	No
Pentaglobin in resistant infections	Yes	27/Mar/2020	1	No	No
PTCY in HLA 7/8 matched	Yes	17/Dec/2019	0	No	No
CECinVOD study	Yes	04/Mar/2020	6	No	No
AML2120	Yes	Oct/2020	1	No	No
NEXTFamLY	Yes	24/Jan/2017	13	Yes	Yes
DEMONSTRATE	Yes	Nov/2019	0	No	No
NGS-dPCR-AML study	Yes	Oct/2020	2	No	No
VEN-DEC study	Yes	25/Sept/2020		No	No

# DLI in Acute Leukemia: GITMO-DLI



## Allogeneic stem cell transplantation (ALLO-SCT) in elderly: 17-years retrospective GITMO Survey

### Type of study:

Retrospective observational

### Primary objective:

Overall survival (OS) at 12 months after DLI administration



PI: Prof Michele Malagola

# Donor-specific anti-HLA abs: GITMO AIBT DSAs



Anticorpi anti-HLA donatore-specifici (DSAs) nei pazienti candidate a trapianto  
allogeneico mismatched – Studi GITMO – AIBT DSAs

**Type of study:**

Observational

**Primary objective:**

To evaluate the activity of  
research and monitoring of  
anti-HLA Ab to try to draw  
up common lines of  
behavior among all the  
Italian transplant centers

PI: Prof Domenico Russo

# Elastometry in VOD: ELASTOVOD

Studio prospettico multicentrico per valutare il potenziale diagnostico dell'elastometria epatica di score biochimici e strumentali di predire lo sviluppo di complicanze severe del fegato in pazienti sottoposti a trapianto di cellule staminali emopoietiche (TCSE) - ELASTOVOD

**Type of study:**

Interventional

**Primary objective:**

Individuare dei valori rilevati con TE e score biochimici pre-trapianto e/o un loro incremento come fattore indipendente di aumentato rischio di sviluppare una epatopatia trapianto-correlata.

PI: Prof Domenico Russo

# cGVHD according NIH criteria: GITMO-GVCrOSY

A prospective observational study for evaluating incidence, severity and outcomes of Chronic Graft-versus-Host Disease according to 2015 NIH consensus criteria

**Type of study:**

Prospective observational

**Primary objective:**

To evaluate long-term efficacy of different therapies through the hard outcome failure free survival (FFS).

PI: Prof Domenico Russo

# Pentaglobin in resistant infection - PENTALLO



Pentaglobin as early adjuvant treatment for febrile neutropenia in acute leukemia or allogenic hematopoietic stem cell transplant patients colonized by carbapenem-resistant Enterobacteriaceae or *Pseudomonas aeruginosa*

## **Type of study:**

Prospective observational

## **Primary objective:**

To demonstrate that the early addition of Pentaglobin to the best available antimicrobial therapy is able to reduce mortality and improve survival in neutropenic febrile acute leukemia or allo-HSCT patients colonized by carbapenem-resistant Enterobacteriaceae (CRE) or by any *Pseudomonas aeruginosa* (PA)

PI: Prof Michele Malagola

## PTCY in HLA 7/8 matched

Post transplant high-dose cyclophosphamide as GvHD prophylaxis in patients receiving 1-antigen/allele HLA mismatched (7/8 matched) unrelated hemopoietic cell transplantation for myeloid malignancies

### **Type of study:**

Prospective observational

### **Primary objective:**

To demonstrate that the early addition of Pentaglobin to the best available antimicrobial therapy is able to reduce mortality and improve survival in neutropenic febrile acute leukemia or allo-HSCT patients colonized by carbapenem-resistant Enterobacteriaceae (CRE) or by any *Pseudomonas aeruginosa* (PA)

PI: Prof Domenico Russo



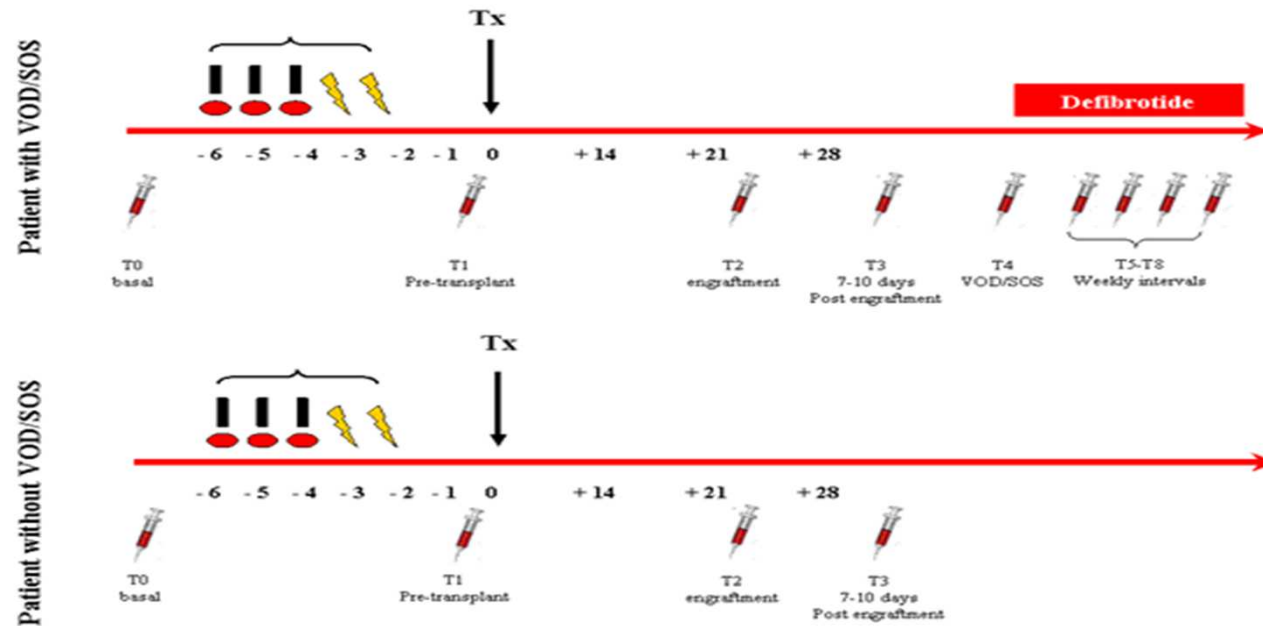
# CECinVOD study

Pilot study on the role of Circulating Endothelial Cells (CEC) as biomarker of endothelial damage in allo-transplanted patients at high risk of hepatic veno-occlusive disease/sinusoidal obstruction syndrome (VOD/SOS) – CECinVOD Study

**Type of study:**  
Observational

**Primary objective:**

To assess the number and trend of the CEC in patients undergoing MAC allo-HSCT and who are at risk to develop VOD/SOS or who actually develop VOD/SOS



PI: Prof Domenico Russo

# AML2120

A retrospective and prospective multicentre observational study of the evaluation of incidence of Familial Acute Leukemia (AML) and Myelodysplastic Syndromes (MDSs) in patients with myeloid neoplasm (AML/MDS)

**Type of study:**

Retrospective, prospective  
and observational

**Primary objective:**

To evaluate the incidence of familial AML/MDSs in patients with de novo MDSs or AML with almost one relative affected by hematological neoplasm and/or other cancers at young age (<40 years)

PI: Prof Domenico Russo

# NEXT-FAMILY 1016

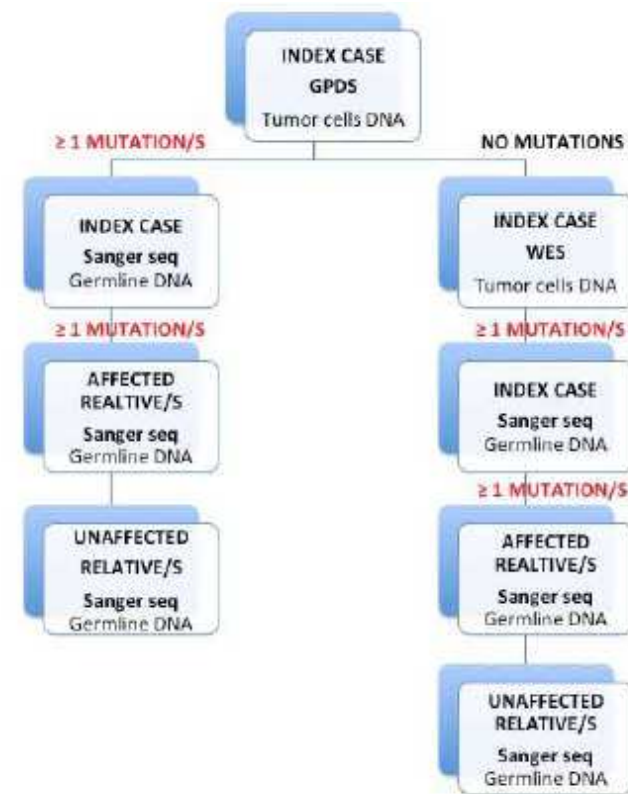
Next generation sequencing (NGS) approach to study known and new germline mutations in familial acute myeloid and myelodysplastic syndromes

## Type of study:

Retrospectively and prospectively

## Primary objective:

Look for predisposing mutations in patients and relatives affected by AML and MDS with familial history of myeloid or, less frequently, lymphoid malignancies



PI: Prof Domenico Russo

# DEMONSTRATE

## Deep Molecular respoNSe and TRAnscript Type Evaluation by digital PCR

### **Type of study:**

Retrospective and  
prospective

### **Primary objective:**

To establish if there is a real  
difference in the depth level  
and stability of deep  
molecular response (DMR)  
between CML patients  
harboring e13a2 or e14a2  
BCR-ABL1 transcript types.

PI: Prof Domenico Russo

# NGS-dPCR-AML Study



Feasibility Study on Detection And Monitoring of Gene-mutations by Digital PCR (dPCR) NGS Driven in Patients with Acute Myeloid Leukemias (AMLs) and High Risk Myelodysplastic Syndromes (HR-MDSs)

**Type of study:**

Prospective

**Primary objective:**

To evaluate the feasibility of dPCR to detect and quantify gene-mutations identified by NGS in the BM/peripheral blood of AML-HR-MDS patients

PI: Prof Domenico Russo

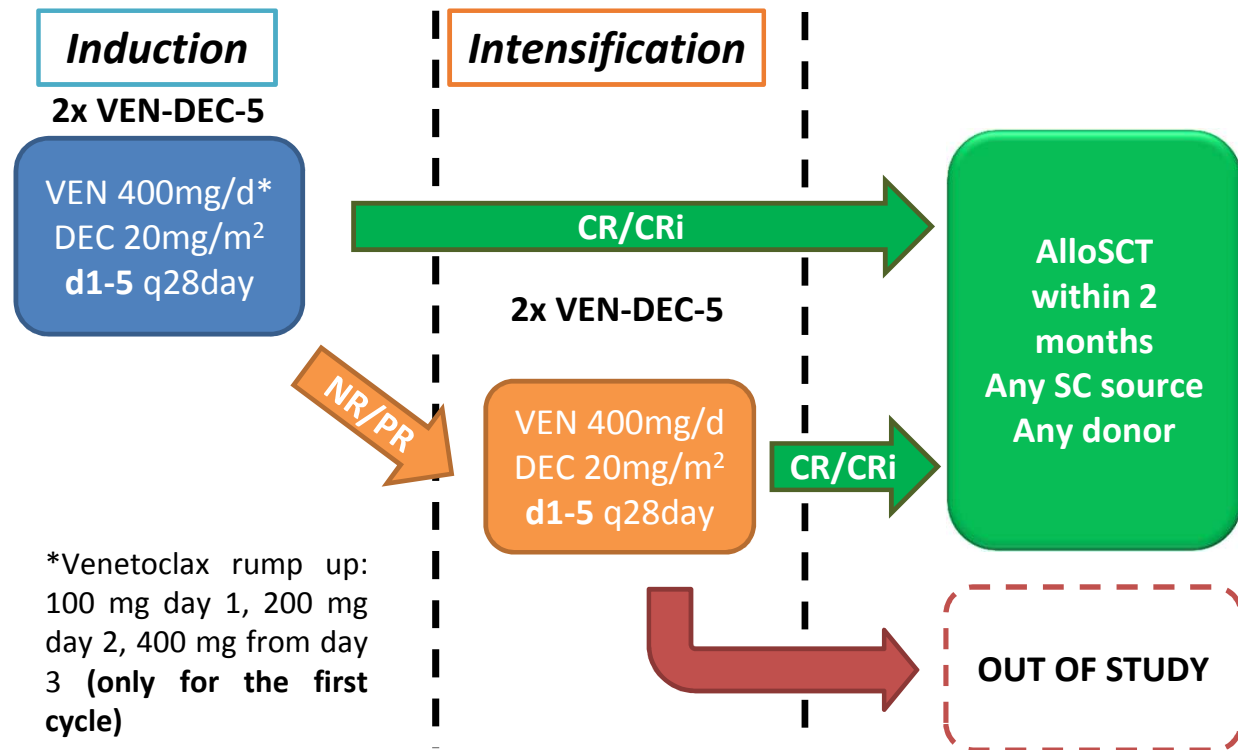
# VEN-DEC Study

Phase II study on Venetoclax (VEN) plus Decitabine (DEC) (VEN-DEC) for elderly ( $\geq 60 < 75$  years) patients with newly diagnosed Acute Myeloid Leukemia (AML) eligible for allogeneic Stem Cell Transplantation (allo-SCT)

## Phase: II

### Primary objective:

Evaluation of number of elderly patient (age 60-75 years) with AML, eligible for allo-SCT, treated with the chemo-free combination VEN-DEC undergoing allogeneic transplantation in CR/Cri/MLFS.



PI: Prof Domenico Russo