



EBMT

European Society
for Blood and Marrow Transplantation

Please return to:

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Proposal for clinical trials

Protocol Title:

EudraCT-Nr.:

IRB vote

yes

no

not requested

requested on _____ (date)
but pending

Investigator(s):

(name and address)

Institution:

Sponsor:

Study type:

Interventional

Within-Lab

Off-Label

Non-Interventional

Single Investigator

Network of Investigators

Study Phase:

Phase I

Phase I/II

Phase II

Phase II/III

Study design:

retrospective

prospective

observational

interventional

single arm

comparative

randomized

open-label

double-blind

single-blind

crossover

parallel

other (*specify*):

Study Rationale

Research hypothesis:

Treatment

Study design:

Study procedure:

Primary Objective:

Secondary Objective(s):

Primary Endpoint (measure of outcome):

Main inclusion:

Inclusion Criteria:

Exclusion criteria:

Planned timeline:

for enrolment:

for follow-up:

Sample size calculation:

Expected enrolment:

Statistics:

Recruitment:

by center

by registriy

by country

by working group

Budget estimate:

Financing:

Industrial collaboration: **yes** **no**

Reviewers for proposed trial evaluation:

Modalities of data collection:

questionnaire	online	paper
registry	CRF	