



## Trial Proposal Template

<b>General Information</b>	
Hematologist (PI)	
Study Title	
Primary Objective	
Study phase	
ASCT single or double	
Maintenance Y/N (fixed duration or until progression)	
Study population (age, newly diagnosed or relapse/refractory)	
Pharmaceutical Company Involved?  Contact person	Yes/No If yes, which:
Budget or drug agreed with pharmaceutical company?	Yes/No If yes provide details:
Data sharing with company?	Yes/No
<b>Logistics</b>	
Potential countries involved	
Number of centers required	
Estimated number of centers per country	
Number of patients required	
<b>Timelines</b>	
Expected recruitment rate	XX patients per year
Planned First patient in (FPI)	
Planned last patient in (LPI)	
Expected treatment duration per patient	
Duration of FU period	
<b>Drug information</b>	
Which drugs are involved?	
Investigational Medical Products (IMP)?	

Which drugs are provided to participating sites?	
<b>Central labs</b>	
Central labs involved?	Yes/No If yes provide details (if known):
Already approached?	
Analyses performed in the central lab?	
<b>CRO</b>	
Will a CRO be used for the study?	Yes/No If yes provide details (if known):
<b>Services required from EMN</b> Contracting and budgeting must be arranged via EMN financial manager	
Trial Management?	Yes/No. If no please provide details:
Development of e-CRF?	Yes/No. If no please provide details:
Central data management?	Yes/No. If no please provide details:
Monitoring?	Yes/No. If no please provide details:
Safety desk?	Yes/No. If no please provide details:
Statistical support?	Yes/No. If no please provide details:
Contracting/budgeting?	
<b>Study procedures</b> (extra cf. Standard of Care)	
Labs	
Radiology	
PET	
Sub studies	
Assessment for toxicity or drug (eg. cardiac toxicity, LVEF, FEV, etc)	
Bone marrow:	
<ul style="list-style-type: none"> <li>• Cryopreservation</li> </ul>	
<ul style="list-style-type: none"> <li>• Cytogenetics analysis/FISH</li> </ul>	
<ul style="list-style-type: none"> <li>• MRD/NGS/NGF</li> </ul>	
Quality of Life	



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Mail completed form to EMN Secretariat [secretariat@emn.org](mailto:secretariat@emn.org)

**Please attach also:**

- 1) a preliminary/draft of synopsis and budget
- 2) PI curriculum vitae