End of Study report

I General information	
EudraCT number:	2011-006239-44
NL number:	NL37601.042.11
Title: *An international collaborative study to discontinue Imatinib/Glivec® in pediatric CML patients with sustained complete molecular response (STOPIMAPED)*	
Sponsor	Stichting Kinderoncologie Nederland (SKION), Dutch Childhood Oncology Group (DCOG)
Participating sites	☐ singlecenter:
	☒ multicenter
Principal Investigator	Prof. Dr. E.S.J.M. de Bont

II Study status	
☐ Terminated as planned	End date of study:
☒ Early Termination	End date early termination: 01-JUL-2014
Reason for early termination: • *The results of a prospective French study in adolescents and adults showed a highly significant and favorable outcome. This made further continuation of the present study unnecessary and unethical. The treatment guideline has been updated based on the French study.* • *Rolling out and implement this study in other potential participating countries and centers proved complex in practice. As a result, recruitment both nationally and internationally fell behind the intended schedule.*	
How many participants were included at the time it was decided to terminate the study early? What are the consequences for these participants? *Only one participant has been included (Site UMCN Nijmegen), there are no negative direct consequences for this participant.*	
What are the consequences of the early termination for the study results? *No statistical analysis on these results is feasible. We won't be able to answer the primary and secondary research questions of the study. However, these questions were answered by the French study and the standard treatment guidelines were modified.*	

III Status inclusion	
How many participants are included in the study?	1
What is the total number of participants that needed to be included according to protocol?	60
What is the cause for not reaching the intended number of participants? • *Delay in implementation of the study in other countries and participating sites* • *Disclosure of results of a similar study*	

IV Report drafted by	
Name and function:	J. Mur, Trialmanager
Date report:	01-APR-2023