

Substantial Amendment

Generic Imatinib and Data Sharing- including Protocol version 2.1

Documents for Sites (please note a number of documents that are not considered to be essential for local review and are not required for the Investigator Site File have not been circulated. These are available from the SPIRIT Office on request).

Document	Version	Date	Notes
Protocol (Clean)	2.1	12 December 2016	Please see the list of changes below
Privacy Notice (Leaflet)	1.0	14 December 2016	
Privacy Notice (Poster)	1.0	14 December 2016	
Substantial Amendment Notification Form	Generic Imatinib & Data Sharing	21 December 2016	Please note section E.1 of the notification of substantial amendment form refers to amendment number 49 However the amendment was subsequently re-numbered by the REC to be amendment 50. This amendment follows amendment 45 (which introduced Protocol version 2.0) in terms of amendments requiring action by all sites. The SPIRIT 2 amendments between numbers 45 and 50 have been PI changes therefore do not apply to all sites.
Covering Letter to REC	Generic Imatinib & Data Sharing	14 December 2016	
REC Approval for Substantial Amendment	Generic Imatinib & Data Sharing	20 January 2017	
HRA Categorisation of Amendment Email	Generic Imatinib & Data Sharing	06 January 2017	
HRA Amendment Approval Email	Generic Imatinib & Data Sharing	03 February 2017	
Covering Letter to MHRA	Generic Imatinib & Data Sharing	14 December 2016	
MHRA Approval for Amended CTA	Generic Imatinib & Data Sharing	24 January 2017	The MHRA refer to this as amendment 49 as per the notification of substantial amendment form. This is not the same numbering as used by the REC however it does refer to the same amendment as evidenced by the amendment description

Protocol Changes (version 2.0 to 2.1)

Change	Section(s)
Information regarding the use of generic imatinib	8.1
Removal of the requirement for bone marrow aspirate samples	10.2
The paragraph relating to planned hospital stays and SAEs, which was added in error as part of the previous amendment, has been removed	11.3
Correction of typographical errors and inconsistencies	Various

Generic Imatinib

The amendment allows the use of Glivec or generic imatinib. If your site is continuing to use Glivec or have not yet switched to a generic, you can continue to use Glivec for SPIRIT 2 patients.

If you switch to generic imatinib for your SPIRIT 2 patients it is still considered to be IMP. The SPIRIT 2 imatinib label will still need to be applied and accountability maintained. Please refer to the SPIRIT 2 Information for Pharmacists (version 3.0) for further details.

Please note this only applies to SPIRIT 2 imatinib patients who have not yet reached visit 15. Once imatinib patients have reached the end of SPIRIT 2, they are no longer considered to be on IMP (even though they may remain on the same supply) therefore trial labelling and accountability are not required.

Please complete and return the attached acknowledgement slip to confirm whether you will be using generic imatinib for your SPIRIT 2 patients and, if so, what brand of generic will be used.

Privacy Notice

The privacy notices (poster and leaflet) aim to provide information to patients about how their data, collected through the SPIRIT 2 study, will be used in further research about CML.

The majority of patients have already consented to their SPIRIT 2 data being shared with researchers through the SPIRIT 2 Biobank consent form. There are a small number of patients who did not sign the biobank consent form or who have since withdrawn their consent from the study. These patients should receive a leaflet to explain how their data is now being used.

The privacy notices ensure that we are sharing all SPIRIT 2 data with research colleagues in line with the Data Protection Act, 1998.

Please ensure that the poster is displayed in your clinic and that it is visible to patients attending the clinic. If you receive any queries from patients, please reassure them that we are continuing to use their data in the same way that we intended at the beginning of the study. The privacy notices are simply to provide more information about what it will be used for.

If any patients insist that they do not want their SPIRIT 2 data to be shared with other researchers then please inform the trial office immediately.

Once you have received authorisation to implement this amendment at your site. Please contact wendy.banks@ncl.ac.uk to request a Privacy Notice poster. You will then be sent a copy of the poster to display at your site and will also receive copies of the Privacy Notice leaflets, if required.

Next Steps

1. Please ensure that the amendment documents are forwarded to your local R&D office for review
2. Once local authorisation is obtained please ensure that confirmation of this is forwarded to the Trial Office to wendy.banks@ncl.ac.uk
3. Please complete and return the Generic Imatinib Information Slip and the Privacy Notice Request Slip
4. Ensure the amendment documentation is filed in your Investigator Site File

In line with the HRA categorisation email and [UK wide policy on the handling of amendments](#), your site is given 35 days from the date of this notification to raise an objection about the amendment. If we do not hear from your R&D office by **Friday 17 March 2017** it will be assumed that the amendment may be implemented at your site.

If more time is needed for consideration of the amendment please contact the SPIRIT Office on 0191 282 0904 or email wendy.banks@ncl.ac.uk.

If you are able to notify us ahead of this date that you are able to implement this amendment it will enable us to potentially implement it sooner.

Please note that, in line with the HRA categorisation email, we will not implement this amendment at a site which requests more time to consider the amendment until we receive confirmation from the site that the amendment can be implemented.

SPIRIT 2 Generic Imatinib Information Slip

Site Name		Site Reference	
PI Name			
Will Generic Imatinib be used for the SPIRIT 2 patients at your site? YES <input type="checkbox"/> NO <input type="checkbox"/>			
If yes, which brand will be used?			
Form Completed by			
Name			
Role			

Please complete and return to the SPIRIT Office by fax (0191 376 0748) or email
wendy.banks@ncl.ac.uk)