

# Interpharm Consultancy

BA Research – Team Experience: Biosimilar Projects							
Drug	Indication	Phase	No. of Patients	No. of Sites in India	Recruitment Rate	Submission	Remarks
G-CSF	Chemotherapy induced Neutropenia	III	104	6	4.33 patients/site/month	DCGI/EU	Study is completed and product is marketed in India and Europe
Erythropoietin	Cancer Induced Anemia	III	60	6	2 patients/site/month	DCGI	Study is completed and product is marketed in India
Erythropoietin	Anemia due to Chronic Kidney Disease	III	60	6	3 patients/site/month	DCGI	Study is completed and product is marketed in India
Interferon	Chronic Myeloid leukemia(CML)	III	40	3	2.22 patients/site/month	DCGI	Study is completed and dossier was submitted to the DCGI
Interferon	Hepatitis B(HBV) and Hepatitis C (HCV)	III	40 in each protocol	6	1.5 patients/site/month	DCGI	Study is completed and dossier was submitted to the DCGI and later the product is launched.
PEG G-CSF	Design of PK study in Humans						

Activities Undertaken	
<ul style="list-style-type: none"> <li><input type="checkbox"/> SOP development for the department</li> <li><input type="checkbox"/> Scientific inputs in the Protocol and Statistical Analysis</li> <li><input type="checkbox"/> Preclinical development activities</li> <li><input type="checkbox"/> Regulatory activities.</li> <li><input type="checkbox"/> Feasibility</li> <li><input type="checkbox"/> Site Selection</li> <li><input type="checkbox"/> Ethics Committee Submission and EC approval</li> <li><input type="checkbox"/> Initiation of the trial</li> <li><input type="checkbox"/> Tracking the progress of the trial</li> <li><input type="checkbox"/> Monitoring of the trial</li> <li><input type="checkbox"/> Providing strategy for Recruitment Enhancement</li> <li><input type="checkbox"/> Preparation of study documents; Protocol, ICF, SAE Form, CRF.</li> <li><input type="checkbox"/> Preparation of various Study Trackers and Study user manual</li> <li><input type="checkbox"/> Preparation of IP packaging and coordination of IP supply</li> <li><input type="checkbox"/> Vendor Management</li> <li><input type="checkbox"/> Literature search for Oncology products and protocols</li> <li><input type="checkbox"/> Overall Site management &amp; Project Management including Budget and Recruitment</li> </ul>	<p><b>BA Research is represented in Europe by:</b>  <b>Peter Wittner</b>  <b>Interpharm Consultancy</b>  <b>55 Northiam, Woodside Park</b>  <b>London N12 7JH</b>  <b>Tel/Fax: 020-8446-5572</b>  <b>Mobile: 07767-820-852</b>  <a href="http://www.interpharm-consultancy.co.uk">www.interpharm-consultancy.co.uk</a>  <a href="mailto:Peter@interpharm-consultancy.co.uk">Peter@interpharm-consultancy.co.uk</a></p>