



Cytori Therapeutics K.K.
Otemachi Park Building 7F
1-1-1 Otemachi, Chiyoda-ku, Tokyo 100-0004 Japan
TEL: +81.3.6860.5700 FAX: +81.3.6860.5705

INVESTIGATOR INITIATED STUDY (IIS) PROGRAM

SUBMISSION FORM

INVESTIGATOR AND SITE INFORMATION		
First Name:	Last Name:	Title:
Specialty:	Phone:	
Email:		
Hospital/ Clinic Name and Address:		
Facility Type:	<input type="checkbox"/> Public Hospital <input type="checkbox"/> Private Hospital <input type="checkbox"/> University Hospital <input type="checkbox"/> Clinic	
	<input type="checkbox"/> Other – please specify _____	
Name of IRB and/or Ethics Committee:	Frequency/ Schedule of IRB meetings:	
Submission deadlines:	Estimated review time:	

STUDY OVERVIEW INFORMATION	
Study Type: <input type="checkbox"/> Clinical <input type="checkbox"/> Preclinical <input type="checkbox"/> Other – please specify _____	Indication/ Area of Interest:

NATURE OF REQUEST TO CYTORI	
Support Requested:	
<input type="checkbox"/> Medical/ Scientific Information	<input type="checkbox"/> Treatment Protocol Template <input type="checkbox"/> Product
<input type="checkbox"/> Data Collection Support	<input type="checkbox"/> Publication Support
<input type="checkbox"/> Other – please specify _____	



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Study Project Description (including hypothesis and objectives, study title, phase of research (i.e. pre-clinical, clinical within current indication, clinical in unapproved indication), population to be studied (number of subjects, inclusion/exclusion criteria) treatment regimen, endpoints, enrolment and approximate study dates). Please use additional pages if needed. Description should be less than 5 pages.

Study Title:

Background and Rationale:

Hypothesis:

Objectives:

Study Design (i.e. open-label, controlled, blinded, cohort, randomized):

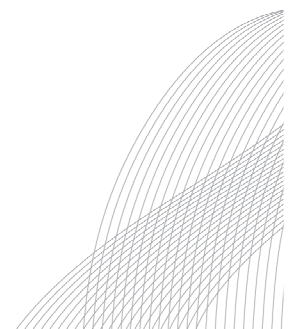
Study Population (number of subjects, inclusion/exclusion criteria):

Endpoints:

Data Analysis:

Timeline:

References:





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REQUIRED DOCUMENTS CHECKLIST
(Please provide the following documents)

- Submission Form (i.e. this application)
- Submission Agreement
- Curriculum Vitae/Resume of Investigator (Note: curriculum vitae of co-investigators or staff who will participate in the study may be submitted but are not required)

If the following are available, they may be submitted:

- IRB/Ethics Committee Approval Letter
- Draft Informed Consent (if clinical study)

Thank you for taking your time to complete this form.

Please return form via email to: contactjp@cytori-jp.com.

Allow 4-6 weeks for Cytori's Scientific Review Committee to review your submission.

Completed by:

(Print name)

Date:

(Signature)

(dd/mm/yyyy)

