CLINICAL STUDY AGREEMENT

DATED Month dd, yyyy

BY AND BETWEEN

National Cancer Center Hospital

AND

XXXXX Hospital

THIS Clinical Study Agreement ("Agreement") is made and entered into as of Mmm dd, yyyy ("**Effective Date**") by and between National Cancer Center Hospital ("**Sponsor**") with its principal business office located at 5-1-1 Tsukiji, Chuo-ku, Tokyo 104-0045, Japan and **XXXXX Hospital ("Institution")** with its principal business office located at XXXXXXX and **Dr. XXXXXX**, an Institution's investigator **("Principal Investigator")** with its principal business office located at XXXXXX.

WHEREAS, Sponsor is an institution which takes responsibility for the initiation, management, and/or financing of the clinical study for the protocol No. NCCHXXXX, entitled "protocol title" (the "**Protocol**") (such clinical study for the Protocol shall hereinafter be referred to as the "**Study**"); and

WHEREAS, Sponsor and Principal Investigator agree that both parties shall participate in the Study in accordance with the terms set out in this Agreement;

NOW, THEREFORE, in consideration of the foregoing and the premises contained herein, the parties hereto agree as follows:

1. Investigators and Research Staff.

1.1 Principal Investigator.
The Study will be conducted by: **Dr. XXXXXXXX**.
The term "**Principal Investigator**" as used in this Agreement refers, as applicable, to Principal Investigator or Institution or both.

1.2 Subinvestigators and Research Staff. Principal Investigator will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Study as subinvestigators or research staff.

1.3 Obligations. Institution will ensure that any Principal Investigator, subinvestigators and research staff ("**Study Personnel**") will abide by all terms of this Agreement applicable to the activities they perform. Institution is responsible to Sponsor for compliance by all Study Personnel with the terms of this Agreement.

1.4 No Substitution. Institution will not reassign the conduct of the Study to a different principal Investigator without prior written authorization from Sponsor

1.5 Delegation of Duties by Principal Investigator. Principal Investigator may delegate duties and responsibilities to subinvestigators or research staff only to the extent permitted by the relevant laws and regulations governing the conduct of clinical investigations.

1.6 Compliance with Institutional Policies. Principal Investigator will comply with the policies and procedures of the organization(s) with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify

Sponsor promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.

2. **Payment**. In consideration of the conduct of the Study by Principal Investigator, Sponsor will make payment to Institution in accordance with Attachment A attached hereto.

3. **Protocol**. No Additional Research. No additional research will be conducted on Study subjects during the conduct of the Study unless it is approved in writing by Sponsor. Such prohibited research activities include, but are not limited to, analysis of biological samples from Study subjects for any non-therapeutic purpose.

4. **Subject Enrollment**. Principal Investigator will enroll in the Study a minimum of ___ but no more than ___ qualified subjects by Mmm dd, yyyy, unless Sponsor extends this enrollment period by written notification. A qualified subject is one who meets all Protocol criteria for inclusion in the Study.

4.1 Excess Enrollment. If Principal Investigator enrolls the maximum number of qualified subjects before the deadline, Sponsor may request Principal Investigator to enroll additional subjects.

4.2 Failure to Enroll. If Principal Investigator fails to enroll the minimum number of qualified subjects before the deadline, Sponsor may terminate this Agreement (see Section 21, Termination).

4.3 Multi-Center Studies. If the total enrollment needed for a multi-center study has been achieved, Sponsor may discontinue subject enrollment early before the end of the enrollment period for the Study or before Principal Investigator has enrolled the minimum number of qualified subjects (see Section 21, Termination). Sponsor will not make payment for further subjects enrolled after the above discontinuation of subject enrollment.

5. **Study Conduct**. Principal Investigator will conduct the Study in accordance with the Protocol, Sponsor written instructions, International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines, and all applicable governmental laws, rules, and regulations.

5.1 No Charging for Reimbursed Services. Principal Investigator will not charge a Study subject or third-party payer for any services reimbursed by Sponsor under this Agreement.

6. **Independent Ethics Committee/Institutional Review Board**. Before the Study is initiated, Principal Investigator will ensure that both the Study including the Protocol and the informed

consent form are approved by an Independent Ethics Committee or Institutional Review Board (as applicable) (both referred to as a 'IRB') that complies with all applicable laws and regulations. Principal Investigator will further ensure that the Study is subject to continuing oversight by the IRB throughout its conduct.

7. **Data Protection**. Principal Investigator must warrant that, as of the date of enrolment of each individual participating as a study subject, it will obtain from each such individual an authorisation that meets the requirements of any applicable privacy rule. Such authorisation shall permit (i) all necessary uses of the individual's "protected health information" by Principal Investigator as part of the clinical study and (ii) all disclosures of such protected health information by Principal Investigator to Sponsor and its authorised agents and the clinical study team and other professionals involved in the clinical study for purposes relating to the clinical study or other purposes permitted by law. Principal Investigator shall take all necessary steps:

a. to ensure that the technical and organisational security measures specified in the protocol and applicable laws and regulations are taken to protect clinical study data against accidental or unlawful destruction or accidental loss or damage, alteration, unauthorised disclosure or access and against all other unauthorised disclosure or access and against all other unauthorised or unlawful forms of processing; and

b. to ensure that Principal Investigator's own employees, as well as any sub-contractors, temporary employees or other third-parties or vendors who have access to any confidential or personally identifiable information relating to the clinical study, receive appropriate privacy and security training, which shall be updated periodically as the laws and regulations evolve.

8. **Biological samples.** If biological samples are collected and transferred, each Party shall ensure that any collection, handling, transportation and retention of biological materials, is carried out in accordance with the Protocol, Informed Consent and all applicable laws, including the Human Biomedical Research Act 2015. Each Party shall ensure that the security, integrity and quality of the biological materials is maintained at all times, and be responsible for maintaining its own chain of custody to allow traceability and management of the biological materials.

9. **Informed Consent and Authorization to Use and Disclose Health Information**. Principal Investigator will provide Sponsor an opportunity to review and approve the content of the informed consent form (including any revisions made during the course of the Study) before it is used. Principal Investigator will obtain a written informed consent from each Study subject and will maintain a signed original of that consent in the subject's record. Principal Investigator

will allow Sponsor to inspect signed informed consent forms or photocopies thereof during monitoring visits or audits (see Monitoring and Audits, Section 14).

10. **Investigational Drug**. Sponsor will provide Institution, at no charge, with sufficient quantities of XXXX (Investigational Drug) and Placebo to conduct Study. Unless otherwise indicated in Attachment A, Sponsor will cover the cost of other study treatment. Protocol-required drug that Sponsor provides or covers the cost is considered "Investigational Drug".

10.1 Custody and Dispensing. Institution will maintain appropriate control of supplies of Investigational Drug and will not administer or dispense it to anyone who is not a Study Subjects, or provide access to it to anyone except Study personnel.

10.2 Use. Institution will use Investigational Drug only as specified in the Protocol. Any other use of Investigational Drug constitutes a material breach of this Agreement.

11. **Adverse Events**. Principal Investigator will report to Sponsor all adverse events experienced by Study subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone or facsimile transmission to the address set forth below, or such other contact information as Sponsor may later provide in compliance with Section 28 (Notices) of the Agreement. Sponsor shall, so far as is lawful, have full responsibility for the reporting of all adverse events to local and international regulatory and/or health authorities.

Facsimile: +81 3 3542 ####

Email: #####@ncc.go.jp

Attention: XXXXX

12. **Confidential Information**.

12.1 Definition. Except as specified in Section 12.2, Exclusions, below, "Confidential Information" means

a. the Protocol,

b. Study Data (as defined in Section 13, Study Data and Study Records, below), subject to Principal Investigator's right to publish the results of the Study (as described in Section 16, Publications, below),

c. any other information related to the Study or technology, research, or business plans that Sponsor provides to Principal Investigator.

12.2 Exclusions. Confidential Information does not include information that

a. is known or open to the public or otherwise in the public domain at the time of disclosure,

b. becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Principal Investigator,

c. is already known to Principal Investigator at the time of disclosure and is free of any obligations of confidentiality, or

d. is obtained by Principal Investigator, free of any obligations of confidentiality, from a third party who has a lawful right to disclose it.

12.3 Obligations of Confidentiality. Unless Sponsor provides prior written consent, Principal Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Principal Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the IRB representatives is specifically authorized.

b. Publication of the results of the Study based on Study Data collected or generated by Principal Investigator is specifically authorized, subject to the provisions of Section 16, Publications, of this Agreement.

12.4 Disclosure Required by Law. If disclosure of Confidential Information to any party is required by law otherwise than authorized under Section 12.3 b, that disclosure does not constitute a breach of this Agreement so long as Principal Investigator

a. notifies Sponsor in writing as far as possible in advance of the disclosure so as to allow Sponsor to take legal action to protect sponsor's Confidential Information,

b. discloses only that Confidential Information required to comply with the legal requirement, and

c. continues to maintain the confidentiality of Confidential Information with respect to all other third parties.

12.5 Return of Confidential Information. If requested by Sponsor in writing, Principal Investigator will return all Confidential Information except that required to be retained at the Institution site by law. However, Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

12.6 Notwithstanding any other provision of this Agreement, Principal Investigator hereby expressly authorizes Sponsor to disclose Confidential Information to the investigational product provider(s) ("XYZ") solely to the extent necessary for Sponsor to fulfill its obligations to XYZ under the Sponsor- XYZ Agreements; provided that XXYZ is under confidentiality obligations at least as restrictive as set forth herein. For the

purpose of this Agreement, "Sponsor-XYZ Agreements" means certain collaboration agreements between XYZ and Sponsor, as amended from time to time, and agreements between Sponsor and XYZ and their Affiliates relating thereto that may be in effect from time to time. The parties agree that this Agreement shall govern any and all obligations with respect to Confidential Information as between Sponsor and Principal Investigator, including but not limited to Confidential Information that is shared, transferred, disclosed, used, and/or sub-licensed to XYZ.

13. Study Data and Study Records.

13.1 Study Data. During the course of the Study, Principal Investigator will collect and submit certain data to Sponsor or its designee, as specified in the Protocol. This may include case report forms or their equivalent ("Case Report Forms"), electronic data records ("Data Records"), X-ray, MRI, or other types of medical images, ECG, EEG, or other types of tracings or printouts, data summaries, or any combination of these (collectively, "Study Data"). Principal Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Principal Investigator will deliver Study Data to Sponsor or its designee within the time periods specified in Attachment A (Clinical Trial Budget Summary) of this Agreement.

13.2 Study Records. Principal Investigator will ensure that subject's Study records, which include Principal Investigator's copies of all Study Data as well as relevant documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a. Retention. Principal Investigator will keep the Study Records, under storage conditions conducive to their stability and protection, for a period of fifteen (XX) years after termination of the Study unless Sponsor authorizes, in writing, earlier destruction. Principal Investigator agrees to notify Sponsor before destroying any Study Records after the required retention period.

13.3 Ownership. Study Data and Study Records are and remained the property of Sponsor. It is understood by Principal Investigator that Sponsor will use such information, etc. obtained during the Study in connection with the development of the drug and therefore may disclose it as required to other investigators or to regulatory agencies.

14. Monitoring, Inspections and Audits.

14.1 Monitoring. Sponsor shall be entitled at its absolute discretion to monitor and audit the conduct of the Study. Upon reasonable notice, Institution will permit Sponsor representatives access to the premises, facilities, procedures and records relating to the Study, and Study Personnel as required to accomplish this. Institution agrees to

co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by Sponsor will relieve Principal Investigator of any of its obligations hereunder.

14.2 Inspections and Audits. Institution agrees to accept the inspection by regulatory agencies worldwide. Regulatory inspections may occur after completion of the Study and may include auditing of Study Records. Auditing involves comparison of Case Report Forms or Data Records with the source documentation on which they are based. Sponsor or XYZ may also audit the Study Records as part of its monitoring of the conduct of the Study.

a. Notification. Principal Investigator will notify Sponsor as soon as reasonably possible if Institution site is inspected or scheduled to be inspected by a regulatory agency.

b. Cooperation. Principal Investigator will cooperate with regulatory agency or Sponsor representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.

c. Resolution of Discrepancies. Principal Investigator will promptly resolve any discrepancies that are identified between the Case Report Forms and the subject's medical records.

d. Inspection Findings and Responses. Principal Investigator will promptly forward to Sponsor copies of any inspection findings that Principal Investigator receives from a regulatory agency. Whenever feasible, Principal Investigator will also provide Sponsor with an opportunity to prospectively review and comment on any Principal Investigator responses to regulatory agency inspections.

15. Study Conduct Evaluations. Sponsor or its external service providers may document and evaluate the performance of Principal Investigator in the conduct of the Study. Sponsor will use these evaluations solely for internal purposes.

16. Publications.

16.1 If Principal Investigator wishes to make any publication or presentation relating to the clinical study, at meetings or otherwise, Principal Investigator shall provide to Sponsor any proposed presentation at least forty-five (45) working days prior to being disclosed and any other proposed publication at forty-five (45) working days prior to being disclosed. Sponsor shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

a. to ensure the accuracy of the presentation or publication;

b. to ensure that proprietary information is not inadvertently divulged;

c. to enable intellectual property rights to be secured;

d. to enable relevant supplementary information to be provided.

Principal Investigator shall be required to comply with any request to amend or delete any statement in a proposed publication, provided such request is based on any one of (a) to (d) above.

Notwithstanding the foregoing, if the clinical study is a multi-centre study, the first publication of data shall be based on consolidated data from all centers analyzed according to the protocol, unless otherwise agreed in writing by all principal investigators involved in the clinical study and by Sponsor.

16.2 Sponsor may require any proposed publication or presentation to be delayed for up to three (3) months to enable a patent application to be prepared and filed. The three (3) months period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the clinical study are made available to Sponsor, whichever is later.

16.3 Authorship of any publications relating to the clinical study shall be determined by agreement with Sponsor.

16.4 Notwithstanding the foregoing, Principal Investigator hereby authorizes disclosure to XYZ in accordance with Section 12. Notwithstanding the foregoing, nothing herein shall prevent or restrict XYZ from making any disclosures of published Study data disclosed to it by Sponsor pursuant to Section 12 or of the existence of this Agreement.

17. <u>Indemnification</u>.

17.1 Sponsor shall defend, indemnify and hold harmless the Institution, Principal Investigator and any agents and employees of the Institution from any liabilities, claims, actions or suits for personal injury or death directly arising out of any clinical intervention or procedure required by the Study to which the Patients would not have been exposed but for their participation in the Study, if:

a. the Study is conducted in accordance with the Protocol, together with all written instructions issued by Sponsor, Good Clinical Practices and this Agreement;

b. the loss does not arise out of the negligence or willful misconduct of any of the Institution or Principal Investigator or their respective agents or employees or any other person on the Institution's property, who is not a Sponsor’s employee;

c. Sponsor is notified within fifteen (15) working days of any complaint, claim or injury relating to the loss; and

d. Sponsor has sole control over the defense and settlement of the complaint or claims.

17.2 Sponsor shall provide a diligent defense against, or a settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity. The Institution and Principal Investigator shall fully cooperate with Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement. If a claim or action is asserted, the Institution and Principal Investigator shall have the right to select and obtain representation by separate legal counsel, as long as Institution and/or Principal Investigator, as the case may be, pay for all costs and expenses incurred in conjunction with representation by such separate counsel.

17.3 Institution and Principal Investigator shall defend, indemnify and hold harmless Sponsor, and any agents and employees of Sponsor, from any liabilities, claims, actions or suits for personal injury or death directly arising from the negligence or willful misconduct of the Institution, Principal Investigator or their representatives.

18. **Use of Name**. Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without prior written permission from the other party. However, Sponsor, reserves the right to identify Principal Investigator and Institution in association with a listing of the Protocol or the Study in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

19. **Assignment and Delegation.**

19.1 By Institution. Institution may not assign its rights or delegate or subcontract any duties under this Agreement without prior written permission from Sponsor. Any attempt to so assign, delegate, or subcontract is invalid. If Sponsor authorizes delegation or subcontracting, Institution remains responsible to Sponsor for the performance of all delegated or subcontracted duties.

19.2 By Sponsor. Sponsor may not assign its rights or delegate its duties under this Agreement without prior written permission from Institution. Any attempt to so assign or delegate is invalid. However, Sponsor may freely subcontract Study-related duties to an external provider upon advance notice to Institution, and also may freely assign its rights or delegate its duties to any Sponsor affiliate. If Sponsor delegates or

subcontracts any duties, Sponsor remains responsible to Institution for the performance of those duties.

19.3 Affiliates. As used in this Agreement, the term "affiliate" means, with respect to a particular party, any entity which directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such party. In this context, "control" means (i) ownership by one entity, directly or indirectly, of more than fifty percent (50%) of the voting stock of another entity or (ii) power of one entity to direct the management or policies of another entity by contact or otherwise.

19.4 Successors and Assigns. This Agreement will bind and inure to the benefit of the successors and permitted assigns of each party.

20. Conflict with Attachments. If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

21. Termination.

21.1 Termination Conditions. This Agreement terminates upon the earlier of any of the following events:

a. Disapproval by IRB. If, through no fault of Principal Investigator, the Study is never initiated because of IRB disapproval, this Agreement will terminate immediately.

b. Study Completion. For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by Sponsor of all Protocol-required data; and receipt of all payments due to either party.

c. Termination Upon Notice. Sponsor reserves the right to terminate this Agreement for any reason upon thirty (30) days prior written notice to Principal Investigator.

d. Immediate Termination by Sponsor. Sponsor further reserves the right to terminate this Agreement immediately upon written notification to Principal Investigator for causes that include, but are not limited to, failure to enroll subjects at a rate sufficient to achieve the Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in Sponsor' opinion pose risks to the health or well-being of Study subjects; or regulatory agency actions relating to the Study.

e. Immediate Termination by Principal Investigator. Principal Investigator reserves the right to terminate this Agreement immediately upon notification

to Sponsor if requested to do so by the responsible IRB or if the termination of the Study is required to protect the health of Study subjects.

21.2 Payment upon Termination. If this Agreement is terminated early in accordance with Section 21.1 (Termination Conditions), above, Sponsor will make a payment equal to the amount owed for work already performed, in accordance with Attachment A, less payments already made. If the Study was never initiated because of disapproval by the IRB (see Section 21.1.a, Disapproval by IRB, above), Sponsor will reimburse Principal Investigator for IRB fees and for any other expenses that were prospectively approved, in writing, by Sponsor.

21.3 Return of Materials. Unless Sponsor instructs otherwise in writing, Principal Investigator will promptly return all materials supplied by Sponsor for the Study, including unused Case Report Forms and any Sponsor -supplied materials.

21.4 Survival of Obligations. The provisions of clauses relating to Confidential Information, Study Records, Inventions, Publications, Indemnification, and Debarment shall continue in full force and in accordance with their terms, notwithstanding the expiration or termination of this Agreement for any reason, notwithstanding the expiration or termination of this Agreement for any reason.

22. Debarment. Principal Investigator must certify that (i) neither Principal Investigator nor Institution nor any person employed by it in connection with the Study has been debarred from participating in clinical studies under any applicable law or enactment; and (ii) if at any time after the execution of this Agreement, Principal Investigator becomes aware that Institution or any person involved with this Study is debarred, or is in the process of being debarred, Principal Investigator will notify Sponsor immediately.

23. Third Party Beneficiary. Principal Investigator agrees that Sponsor may enforce its rights hereunder as a third party beneficiary. In the event that Sponsor is not able to do so for any reason, Principal Investigator agrees that Sponsor may have the benefit of Sponsor's rights hereunder (including without limitation those rights concerning confidentiality and intellectual property) and may transfer such rights and benefits to Sponsor.

24. Modification. Any alteration, modification or amendment to this Agreement must be in writing and signed by each of the parties.

25. Entire Agreement. This Agreement and any Exhibits and Attachments represent the entire understanding between the parties relating to the conduct of this Study. This Agreement

supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.

26. **Force Majeure.** Because of the war, hostilities, revolution, civil unrest, strike, epidemic, fire, storm, flood, or due to any act of God or the affected party causes beyond its reasonable control, resulting in inability to perform obligations, neither party against the other responsible for, nor does it constitute a breach of protocol traffic. When these events result in delays or inability to perform, the party affected by these events should be in writing promptly notify the other party. Such as the delay for twenty-eight (28) days or more, the unaffected party shall have the right immediately after the written notice to terminate this Agreement.

27. **Dispute Resolution.**

27.1 This Agreement shall be construed in accordance with and governed by the laws of XXXXXXX.

27.2 The parties submit to the exclusive jurisdiction and venue of XXXXXXXXX.

28. **Notice**. The Parties will deliver notices and other communications relating to this Agreement by hand, by courier or by a postage-paid traceable method of mail delivery to the mailing address below, or such other address that a Party may later designate by notice to the other Party.

If to Sponsor:
National Cancer Center Hospital
Attention: Dr. XXXXXX
Address: 5-1-1 Tsukiji, Chuo-ku, Tokyo 104-0045, Japan
Telephone: +81 3 3547 ####
Facsimile: +81 3 3542 ####
E-mail: #####@ncc.go.jp

If to Institution:
XXXXX Hospital
Attention: Dr.XXXXXX
Address: XXXXXXXXXXXX
Telephone: ## ## ## ##
Facsimile: ## ## ## ##
E-mail: #####@#####

IN WITNESS WHEREOF, authorized representatives of the parties have executed this Agreement effective as of the Effective Day

[SIGNATURE PAGE FOLLOWS]

Sponsor		**Institution**	
By:		By:	
Name:		Name:	
Title:		Title:	
Date:		Date:	

Principal Investigator

I have read and understand this Agreement and accept the terms as they relate to my activities as the principal Investigator in regard to the Study.

By: _____

Name: _____

Title: _____

Date: _____

Attachment A

(Clinical Trial Budget Summary)

1. Protocol Title:
2. Principal Investigator:
3. Duration of Study:
4. Target Enrolment: X patients
5. Clinical Trial Budget Summary

	Item	Cost per patient (UNIT)	Estimated Total Cost (UNIT) for X patients	Remark
1	Investigator Fee			
2	Examination Fee			
3	Subject Transportation Allowance			
4	Pharmacy Fee			
5	Sub-total			
6	Overhead			
7	Total	-		

6. Pharmacy Fee
7. Record Retention:
8. Payment Schedule
9. Payee information

Table 1. Investigator Fee Payment Milestones

Completed Study Activity	**Budget Per Patient**	**Payment Milestone**
Randomization		
Biological Sample Submission		
End of Treatment: Data Entry Completion		
Follow Up Completion: Data Entry Completion		
Total		

Table 2. Direct Patient Cost in UNIT per patient and total patients

Item	Screening	Treatment																Cost per patient	Total cost for X patients
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	
Cycle/Day	-28 to 0	C1D1	C1D15	C2D1	C2D15	C3D1	C3D15	C4D1	C5D1	C6D1	C7D1	C8D1	C9D1	C10D1	C11D1	C12D1	C13D1	EoT/ with-drawal	
Subject Transportation Allowance																			
Medical Consultation Fee																			
Hematology (hemoglobin, WBC, absolute neutrophil count, platelet count)																			
AST																			
ALT																			
Lactate Dehydrogenase																			
Alkaline Phosphatase																			
Sodium																			
Potassium																			
Magnesium																			
Total Calcium																			
Total Bilirubin																			
Blood Urea Nitrogen (BUN) (or urea)																			
Serum Creatinine																			
Albumin																			
Imaging tests																			
CT/MRI																			
Bone Scant																			
X-ray																			
Tumor Tissue																			
Other																			
XXXXX																			
Total																			