

Institutional Conflict of Interest Management and Monitoring Plan: Takeda Pharmaceuticals Co., Ltd.

The University of Texas MD Anderson (MD Anderson) and Takeda Pharmaceuticals Co., Ltd. (Takeda) are parties to a License Agreement and a Research Agreement (Agreements) pursuant to which MD Anderson and Takeda will collaborate on the conduct of clinical studies involving the MD Anderson technology licensed to Takeda (Studies).

Under the Agreements, MD Anderson has a right to license payments, milestone payments, and royalties. Because of MD Anderson's financial interest in the success of these licensed technologies, MD Anderson has a conflict of interest in regards to the current and any future research conducted by MD Anderson (Studies).

Because MD Anderson is committed to the protection of human subjects and the effective management of its financial conflict of interest in relation to its research activities, MD Anderson has implemented an Institutional Conflict of Interest Management and Monitoring Plan (Plan) to manage and monitor the conflict of interest with respect to MD Anderson's conduct of the Studies. The Plan has been approved by the President of MD Anderson and the Executive Vice Chancellor for Health Affairs for The University of Texas System (EVC) and has been implemented by MD Anderson.

The Plan requirements include:

- MD Anderson employees who have both a financial interest in Takeda and will be involved in the conduct of the Studies will have a personal conflict of interest management plan covering their involvement of the Studies,
- Disclosure of MD Anderson's financial interest to participants in the Studies, to all members of the research teams who will work on the Studies, and in all publications and oral presentations concerning the Studies,
- Posting of this summary on MD Anderson's public website,
- Referral of any concerns/complaints related to MD Anderson's compliance with the Plan, or its financial conflict of interest, to The University of Texas System,
- Recusal of any MD Anderson Institutional Decision Maker who has a financial relationship with Takeda or its known affiliates from negotiations with respect to any agreements or purchasing decisions,
- For any human subjects research subject to this Plan, MD Anderson will disclose both the names of the significant creators of the licensed technology and the fact that they will collectively be entitled to 50% of the license income generated by the Agreements, pursuant to MD Anderson policy,
- For any Clinical Trials, no creator of the licensed technology may serve as a Principal Investigator or Co-Investigator, nor may they enroll patients on said Clinical Trials,
- MD Anderson will not utilize any expanded access, compassionate use, or emergency use investigational new drug applications for any of the licensed technologies subject to this Plan,
- Third party monitoring of the eligibility criteria and safety and efficacy data for any Clinical Trial,
- Oversight of Studies by an external Institutional Review Board (External IRB), including reporting to the External IRB by MD Anderson's Investigational New Drug (IND) Office when applicable,
- Engagement of a non-MD Anderson ethicist (External Ethicist) to address any questions or concerns that participants in the Studies may have pertaining to the MD Anderson financial interest and conflict of interest,
- Supply a copy of the Plan to the External IRB and External Ethicist,
- Review of safety and efficacy data of Studies that are clinical trials by an external and independent Data Safety Monitoring Board (External DSMB),
- Use of multi-institutional trials with a non-MD Anderson lead principal investigator for Studies that are Phase III or Phase II clinical trials aimed at gaining FDA approval under a new drug or biological license application,
- Monitoring activities related to the manufacture of Investigational Agents, if required for the Studies, by MD Anderson's IND Office,

- No creator of the licensed technology may signing-off on, or supervise any individual who may sign-off on, the manufacture of products related to Studies covered by this Plan,
- Reporting to the EVC by an External Contract Research Organization on Studies that are IND-enabling preclinical studies,
- Review and revision of the Plan as necessary with any amendments requiring EVC approval, and
- Annual review of MD Anderson's compliance with the Plan by MD Anderson's Institutional Conflict of Interest Committee and MD Anderson Institutional Compliance, with a report of such review provided to The University of Texas System Ethics Officer.

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