

Institutional Conflict of Interest: DNAtrix, Inc

MD Anderson and DNAtrix, Inc (DNAtrix) are parties to a licensing agreement in connection with which the Board of Regents of The University of Texas System ("Board"), on behalf of MD Anderson, received equity in DNAtrix. This equity will be held, managed and disposed of by the University of Texas Investment Management Company on behalf of the UT System Board of Regents and MD Anderson. Additionally, MD Anderson will receive royalties on net sales of licensed products and milestone payments upon issuance of a patent having a claim covering a product manufactured by DNAtrix and a percentage of consideration received by DNAtrix from its sublicensee(s). DNAtrix will pay MD Anderson minimum annual royalties upon the first sale of licensed product. MD Anderson's equity interest, and rights to payments related to licensed subject matter including DNX-2401, create an institutional financial conflict of interest in relation to research being conducted and to be conducted by MD Anderson including research involving the licensed subject matter (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 using DNAtrix licensed subject matter. 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:

- Oversight of MD Anderson's clinical trials by an external, independent Institutional Review Board (IRB),
- Conduct of phase III studies, or phase II studies aimed at gaining FDA approval, as multi-institutional trials with the lead principal investigator being from an institution other than MD Anderson,
- Review of safety and efficacy data by an external, independent Data Safety Monitoring Board (DSMB),
- Monitoring of manufacturing and testing activities by MD Anderson's Investigational New Drug Office and reported to the IRB,
- Periodic reporting to the EVC or to the Institutional Conflict of Interest Committee (ICOIC) that MD Anderson is organizing,
- Disclosure of the MD Anderson financial interest to all clinical trial patients, to all members of the DNAtrix research teams, and in all publications and oral presentations concerning the DNAtrix Studies,
- Oversight of MD Anderson's preclinical studies by an external Contract Research Organization (CRO),
- Posting of this summary on MD Anderson's public website.
- Engagement of a non-MD Anderson ethicist to address any questions or concerns that DNAtrix clinical trial participants' may have pertaining to the MD Anderson financial interest and conflict of interest,
- Referral of any concerns/complaints related to MD Anderson's compliance with the Plan, or its financial conflict of interest, to the Office of General Counsel for The University of Texas System.
- Prohibition against any MD Anderson institutional decision maker with a financial relationship with DNAtrix being involved in any negotiations with DNAtrix or its known affiliates.

- Annual review of MD Anderson's compliance with the Plan by The University of Texas Systemwide Compliance Officer, with a written report of the review and reports from the CRO, and DSMB to be provided to the EVC.

MD Anderson will modify the Plan, if and when necessary, to address any subsequent matters implicating the integrity of the Studies and to comply with any additional requirements deemed necessary by the EVC to ensure the integrity of the Studies and clinical Trials.

Last updated 3/29/2017