

Safety review of bone growth product ushers in new era of data sharing

June 17 2013

A Yale project involving the independent review of a bone growth product's safety has yielded results, which are published in the June 18 issue of *Annals of Internal Medicine*. The findings are part of the Yale University Open Data Access (YODA) Project's novel partnership with Medtronic, Inc., to study and release all of the company's clinical trial research data on recombinant human bone morphogenetic protein-2 (rhBMP-2).

"This marks the completion of YODA's first initiative and ushers in a new standard of transparency in clinical research," said team leader Harlan M. Krumholz, M.D., the Harold H. Hines Professor of Medicine (cardiology) and director of the Yale Center for Outcomes Research and Evaluation. Krumholz and his colleagues co-authored an editorial on the project in the same issue of *Annals of Internal Medicine* containing the results.

The YODA Project seeks to address the problem of unpublished and selectively published [clinical evidence](#). [Medtronic](#) is the first drug or medical device company to contract with YODA and allow access to all of its [clinical trial data](#) for independent reanalysis.

As part of this project, YODA is releasing two independent reviews of all clinical studies of Medtronic's rhBMP-2 and making the Medtronic data available to people pursuing scientific questions. The YODA team selected the Oregon Evidence-based Practice Center at Oregon Health & Science University in Portland, Oregon, and the Centre for Reviews and

Dissemination at the University of York, United Kingdom to conduct the reviews after an open competition.

These review organizations are also publishing academic papers on their findings in the *Annals of Internal Medicine*. An editorial in the same issue by the YODA team expresses the hope that this project marks a major step toward a cultural shift in thinking about data sharing.

According to the YODA team, publication of the rhBMP-2 reviews is "an historic moment in the emerging era of open science."

"This project demonstrates what is possible when industry and academia work together for the common good, seeking to change assumptions about what is possible and to reset expectations about how best to serve society's interests," said Krumholz, who is also a professor of investigative medicine and public health, and is director of the Robert Wood Johnson Clinical Scholars Program.

"Open science and data sharing will create scientific enterprise that is better able to meet the needs of the public and is a sign of a company that is willing to compete in science rather than marketing," Krumholz added. "Let's hope that others adopt a similar approach."

More information: www.annals.org/article.aspx?doi=10.1093/annals/aml009

Provided by Yale University

Citation: Safety review of bone growth product ushers in new era of data sharing (2013, June 17) retrieved 10 May 2024 from <https://medicalxpress.com/news/2013-06-safety-bone-growth-product-ushers.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.