Access to FDA Research

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OSI Mission

Strengthen credibility of agency science by:

• Helping ensure legitimacy of research
• Resolving disputes of decision-making
• Fostering a culture of scientific integrity
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OSTP Initiatives

Management of Scientific Collections

Public Access to Research Results
Why am I here?
There's one issue that I just want to highlight because I sit on another agency's board, too, and it is a hot topic, and it's all about the public access to data -- underlying data behind publications and generally federally-funded work. I'd be very interested in seeing your approach to this. This is quite a controversial subject as you -- as you step
Dr. Goldman:

way to move this forward? Nobody disagrees with the idea of transparency and being able to, you know, do meta-analysis and access the data in a standardized way. But also nobody wants an unfunded mandate either, or it's just an impossible task of in perpetuity maintaining data sets that, you know -- I mean, we all know a study we might want to utilize from 30 years ago, those data are on a tape somewhere that nothing can read, right? So, I mean,
Science Board – November 20, 2014

Dr. Ostroff:

7 And possibly one of the things that we could put on the
8 agenda for the next meeting is to have a discussion
9 about this, and we can have Nathan Doty, who's leading
10 that, come in and speak with us.
Increasing Access to Results of Gov Funded Scientific Research

OSTP Memo - Feb 2013

Agencies to develop plans to:

Provide **free** digital access to federally-funded, peer-reviewed articles after embargo period

Maximize **free** public access to digital data from federally-funded research
FDA Public Access Plan

Developed through collaboration

Agency-wide
HHS-wide
Government-wide
Public meeting

Published February 27, 2015

www.fda.gov/publicaccessresearch

2 Main Components

Publication Access
Data Access
Publication Access

Articles stored in PubMed Central

• Metadata in PubMed
• NIH infrastructure for article intake

Free full text available to public after 1 year embargo

Articles stored in PubMed Central
Data Access

Data Management Plan (DMP)

- DMPs submitted with request for funding
- Merits of DMP considered in review of request
- DMP balances costs-benefits of preservation and access

Research funding for data management

Data supporting published article made publicly accessible
Summer 2015 – Publication Access and Data Access Policies

Oct 2015 – PMC repository

Jan 2016 – Funding awarded subject to DMP requirements
Pubic Access Trends
Questions?

Concerns?