

Review of Evaluation Process

Methodology

To evaluate the Biorepository Feasibility Study and Demonstration Project, PDA subcontracted with Dean Troyer, M.D., and Dr. Dan Kavanaugh to assist with the evaluation of the methodological integrity of the Feasibility Study surveys. Ann Wendling joined as the Project Manager. The PDA team examined the different models proposed for the biorepository, considering the scientific, ethical and practical merits of virtual, discard and cryopreserved biorepositories (or a combination of these methods). All aspects of the Feasibility Study were assessed for adherence to industry standards, best practices and legislation. After reviewing the final work plan for the University of Connecticut Feasibility Study, an opportunity was identified to produce useful evaluation information in several additional areas. The final Feasibility Study evaluation plan and activities were then formalized (Appendices B, C). The evaluation would also assess the development of cost estimates, the work plans and their implementation, and the overall anticipated success and sustainability of the study considering the proposed business plan for the recommended biorepository.

Due to delays in the Feasibility Study implementation, Drs. Troyer and Kavanaugh were unable to continue on the evaluation team. The DPH was notified of this team change.

PDA Action Steps

Teleconferences

An Introductory Meeting via conference call among the investigators, DPH staff and PDA staff was held on November 29, 2009. On March 22, 2010, a second meeting was held to introduce Ann Wendling, PDA Project Manager, to better understand the project timeline and work plan, to refine the evaluation as necessary and to plan next steps (Appendix G). A third meeting on July 28, 2010 was convened to better understand the U Conn timeline and work plan, to refine the evaluation timeline as necessary and to plan next steps (Appendix H). A last all team meeting was held on Oct. 3, 2011 to assess project progress and anticipated changes in the work plan and deliverables due to significant project delays (Appendix F).

Anne Betzner and Ann Wendling conducted monthly phone calls with Lou Gonsalves, DPH Project Manager from April through December 2011 to discuss project progress and ways to encourage activity toward progress completion by December 31, 2011.

Memoranda

Project progress memos were sent by Anne Betzner and Ann Wendling to Lou Gonsalves on June 17 and Oct 24, 2011 (Appendices D, E). Memos from the PDA team on August 25, 2010 provided feedback on the Pathology Cover Letter and Survey through tracked changes and recommendations for Survey Methodology (Appendices I, J, K).

Interviews

Interviews with Lou Gonsalves, Lloyd Mueller and Barbara Walsh were held during March 2012 to further assess their perspective on the project implementation and conclusions.