Association for the Advancement of Blood & Biotherapies

03/21/23

Individual Donor Assessment

Please check back frequently for updates

FDA has issued a ***draft guidance*** which includes recommendations for evaluating donor eligibility using individual donor assessment questions. This page includes resources to track the latest information and support your understanding as individual donor assessment moves through the regulatory pathway towards implementation.

- AABB's *DRAFT* DHQ v4.0 System of Documents - AABB is stepping outside of the traditional linear process and has submitted the DHQ v4.0 System of Documents to FDA before the final HIV guidance is issued. By making these documents available early and before the final guidance, we hope to remove the some of the "built in" delays of a sequential process. These *DRAFT* documents are not FINAL and must viewed with the understanding that minor revisions may be possible and will be addressed in the Final DHQ v4.0 System of Documents. – 03/21/23
- **Education - FDA's new requirements for PrEP, Individual Risk Assessment, and data supporting these changes** - Peter Marks, MD, PhD, Speaks to AABB Community on FDA's Draft Individual Risk Assessment Guidance (23EL-804) – 02/02/23
    - Dr Mark's slide presentation
- **Link to submit Comments on the draft guidance**: Docket Number: FDA-2015-D-1211
- **FDA's Draft Guidance:** Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry - 1/2023
- **Education (prior to release of FDA's draft guidance)** – Canadian experience shared by Mindy Goldman and Terrie Foster, AABB's advance preparations for the regulatory pathway: Individual Risk Assessment: What You Need to Know as the US Prepares for FDA's Decision (23EL-803) – 01/26/23
- **AABB's Example Model DHQ (prior to release of the draft guidance)** - Individual Risk Assessment Example Model and Test Case Validation Using Canada's Eligibility Criteria – sent to FDA 12/20/22