

U.S. Oversight of Genetic Testing

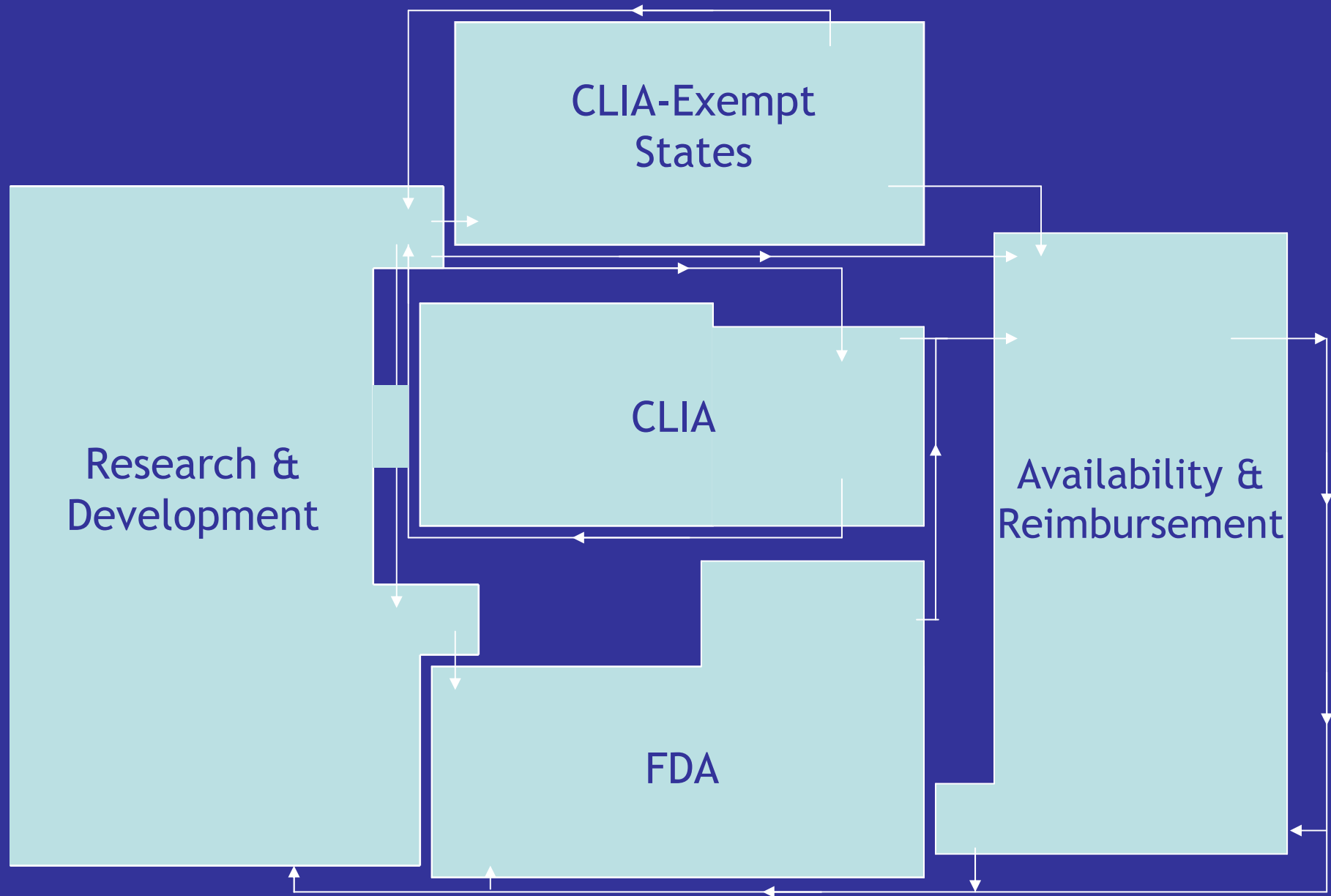
Andrea Ferreira-Gonzalez, Ph.D.
Chair, SACGHS Oversight Task Force

Presentation to the
National Academies Workshop on
Direct-To-Consumer Genetic Testing
August 31, 2009

BACKGROUND

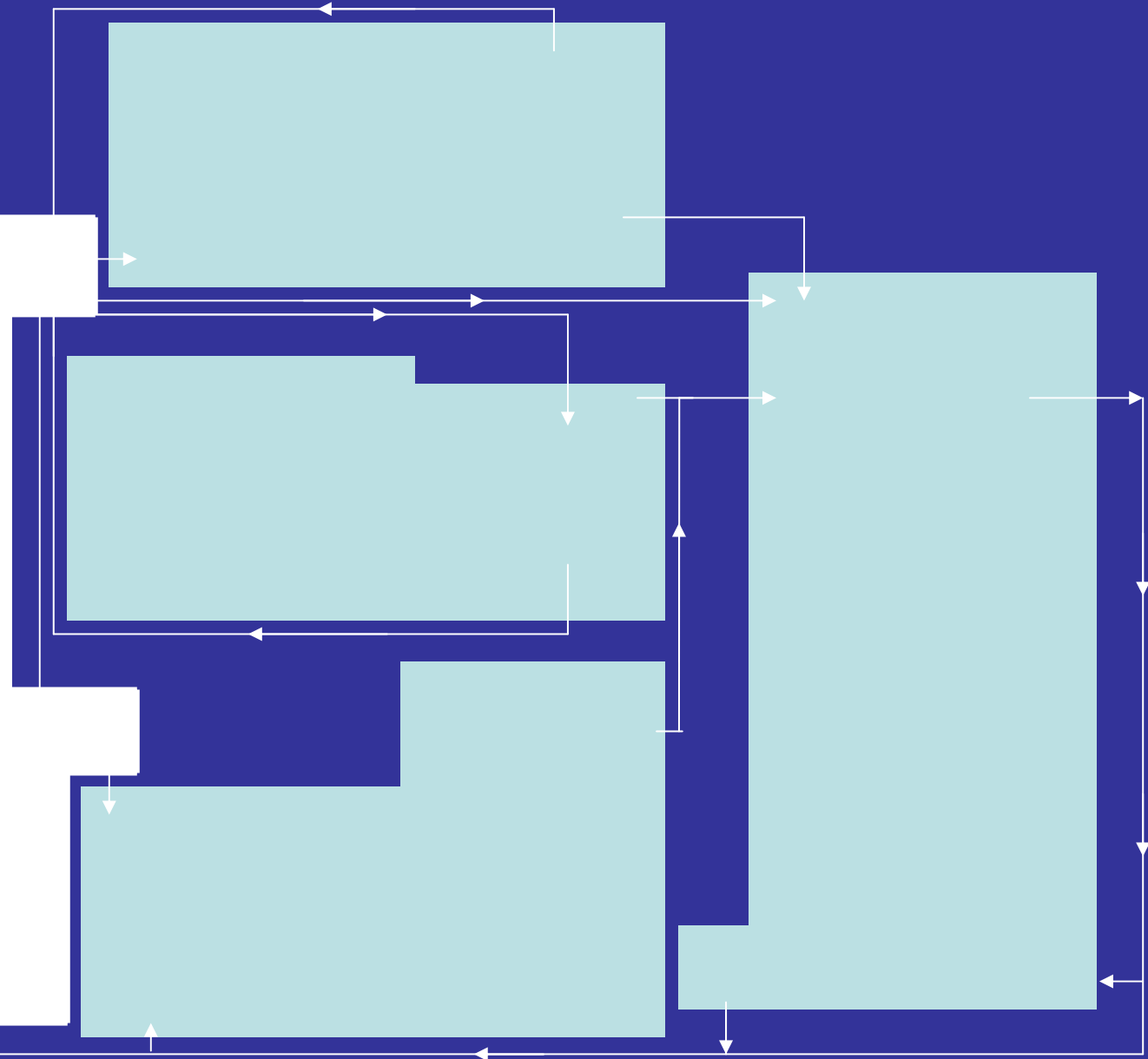
- **March 2007:** Secretary Leavitt charged the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) to investigate specific questions related to the adequacy and transparency of the current oversight system for genetic testing
- **November 2007:** Draft SACGHS report released for public comment
- **February 2008:** SACGHS discussed and finalized 15 recommendations
- **April 2008:** final report completed and submitted to the Secretary

Genetic Testing Oversight Map

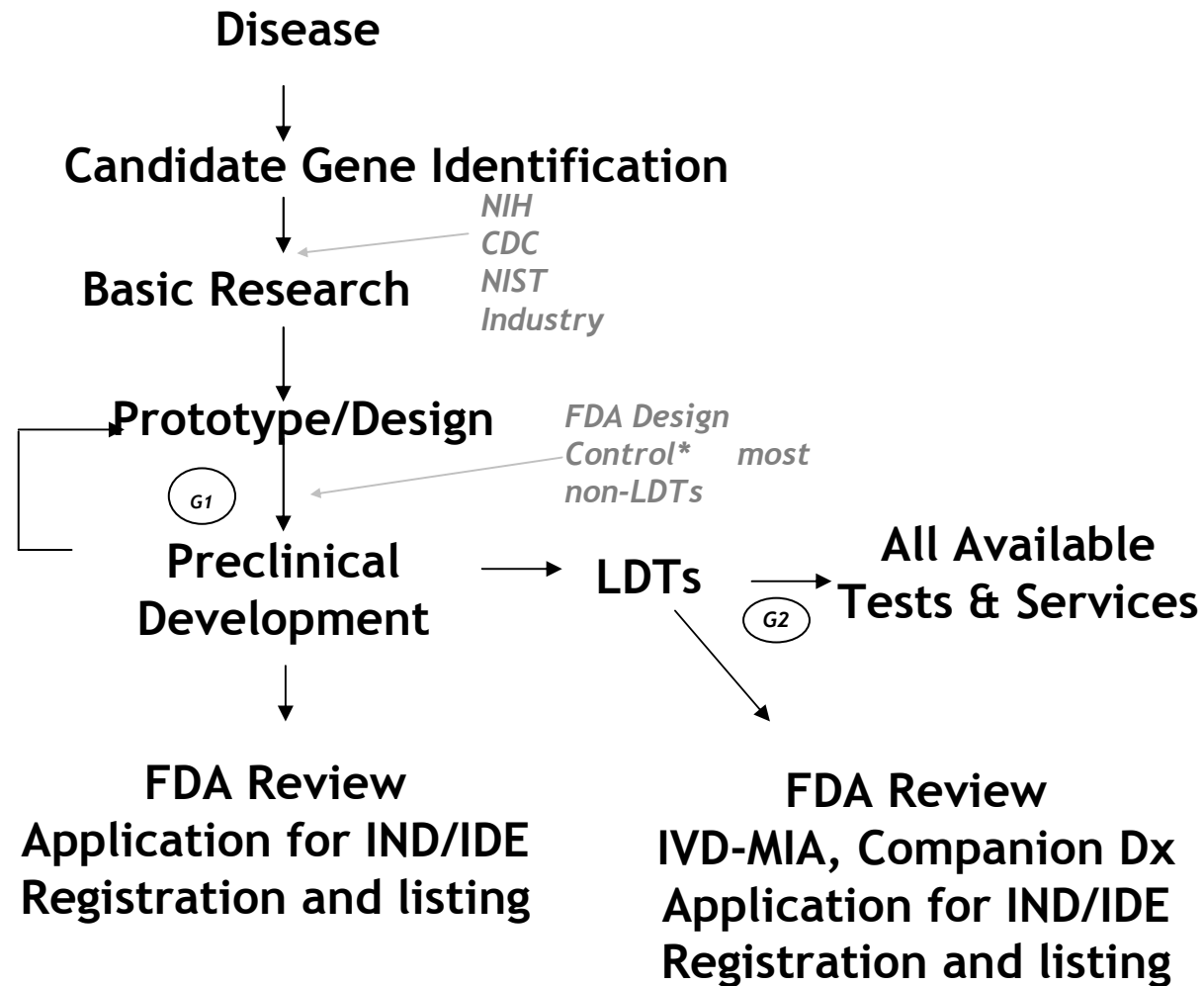


Genetic Testing Oversight Map

**Research &
Development**



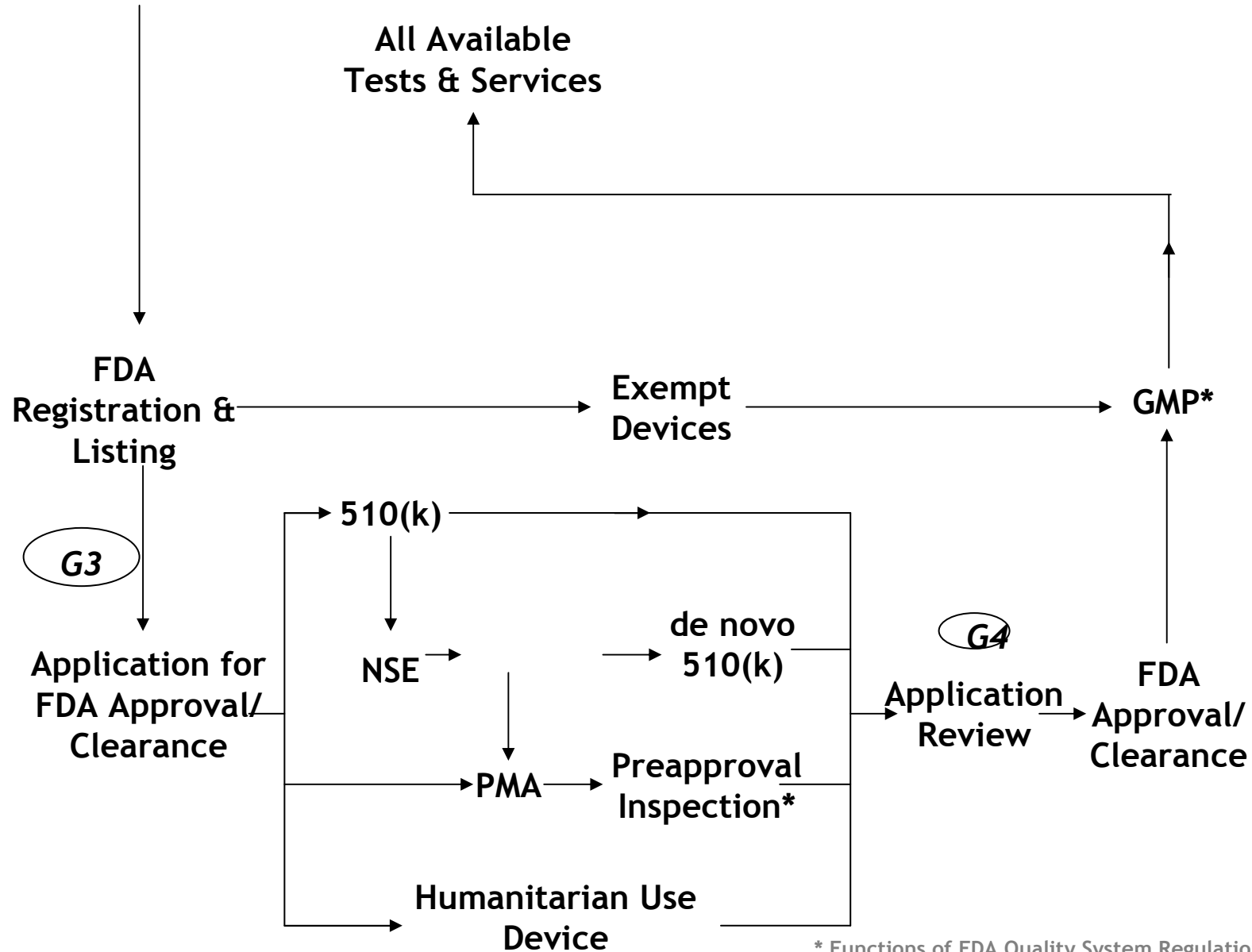
Research & Development



Genetic Testing Oversight Map

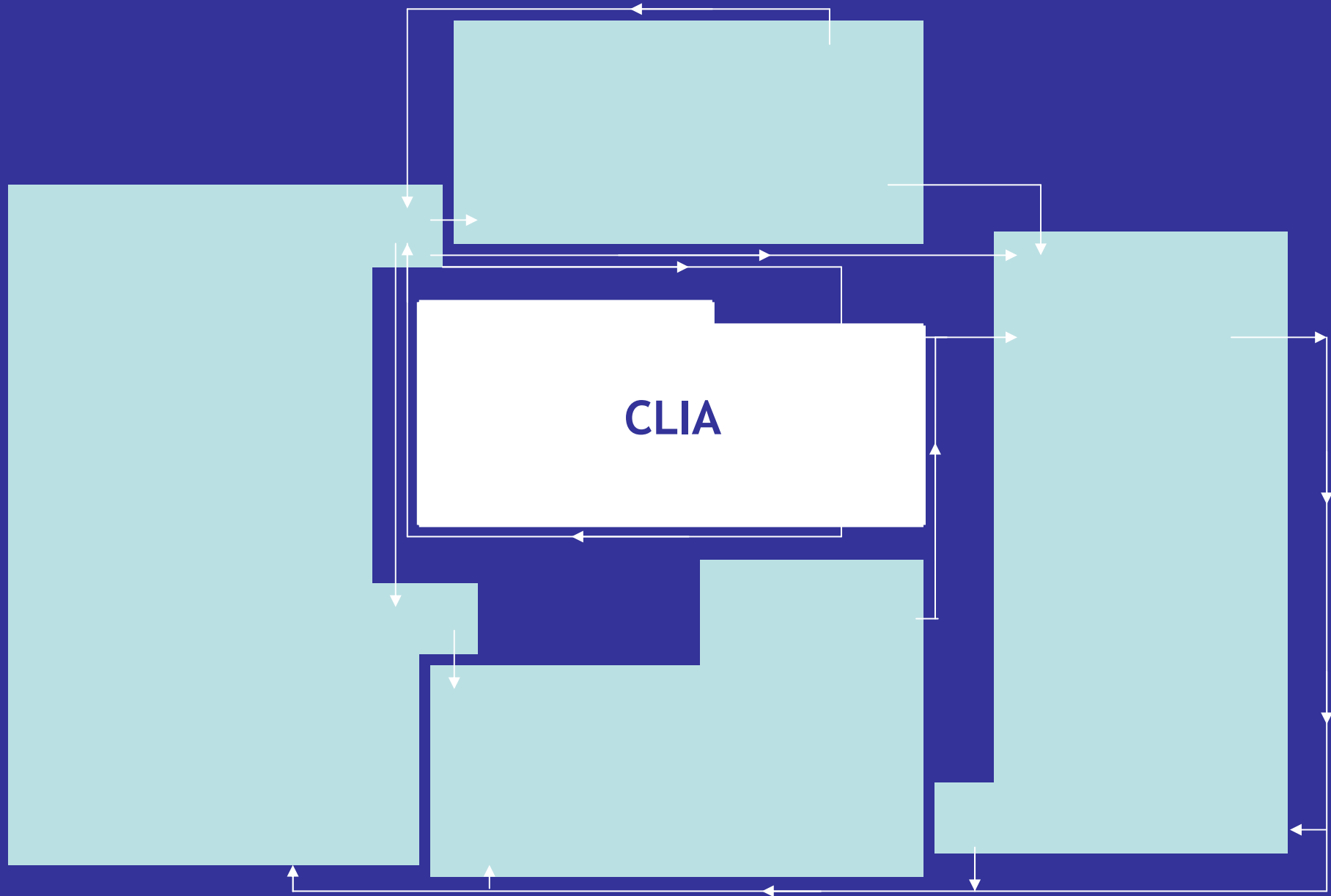


FDA Review

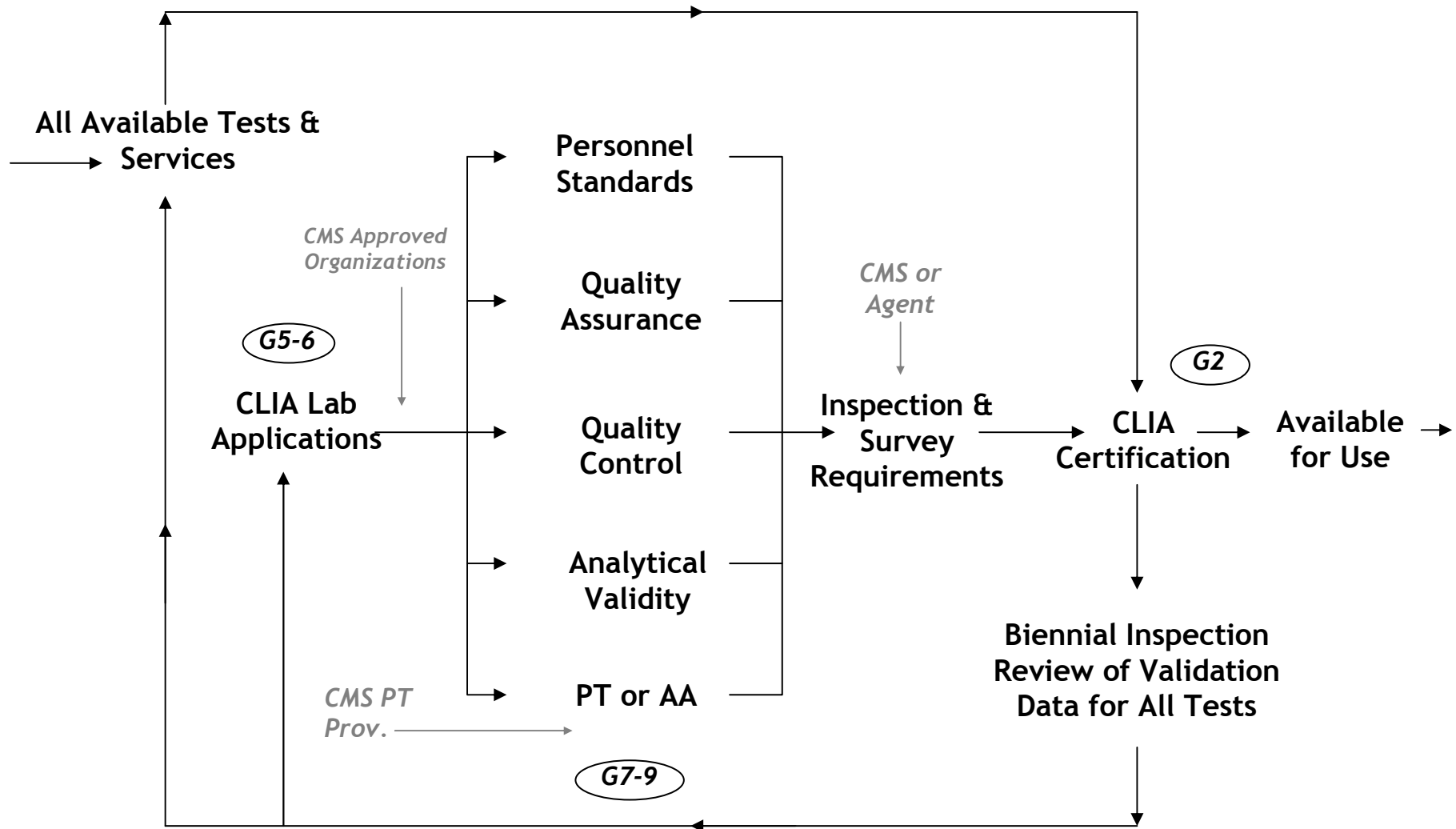


* Functions of FDA Quality System Regulation

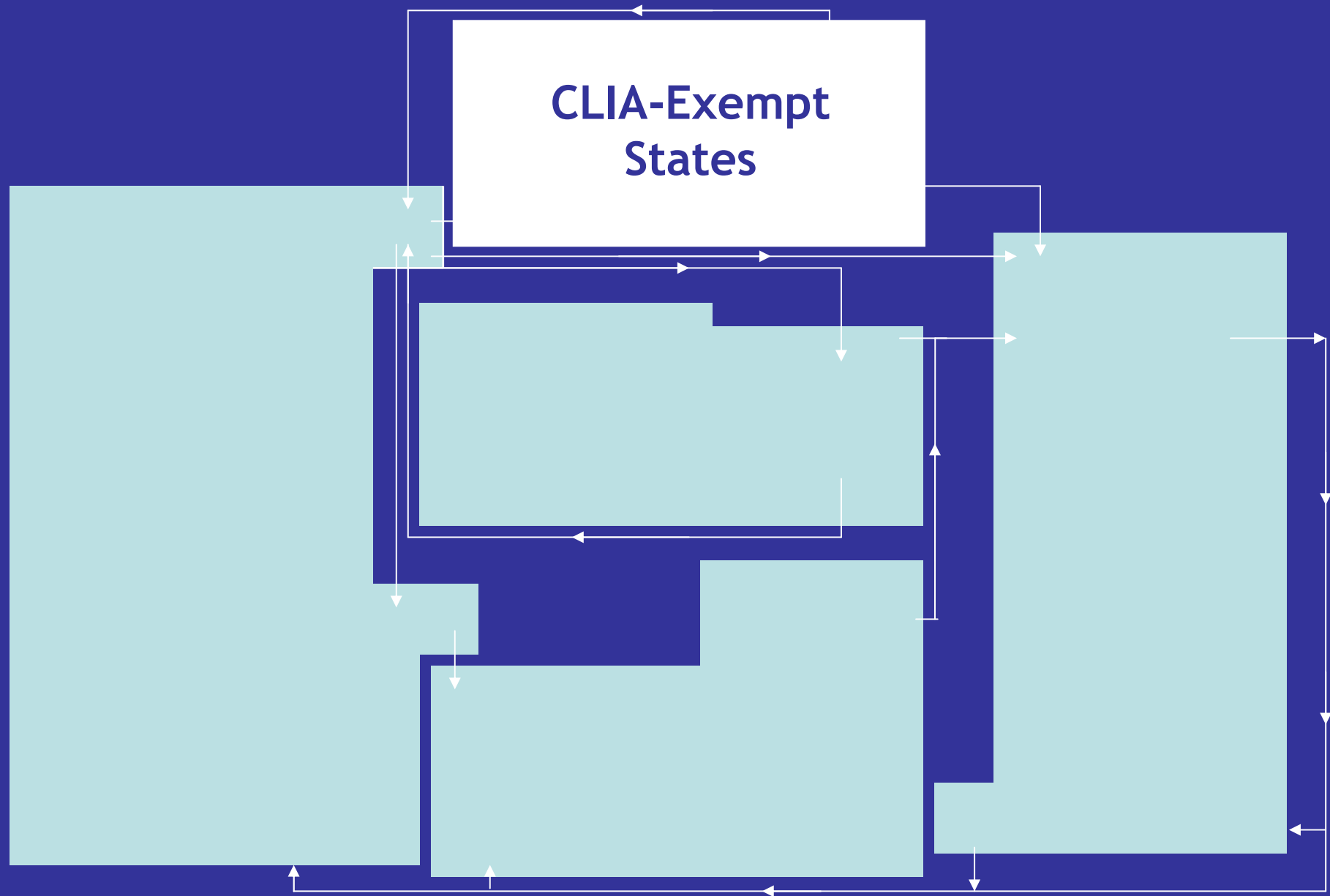
Genetic Testing Oversight Map



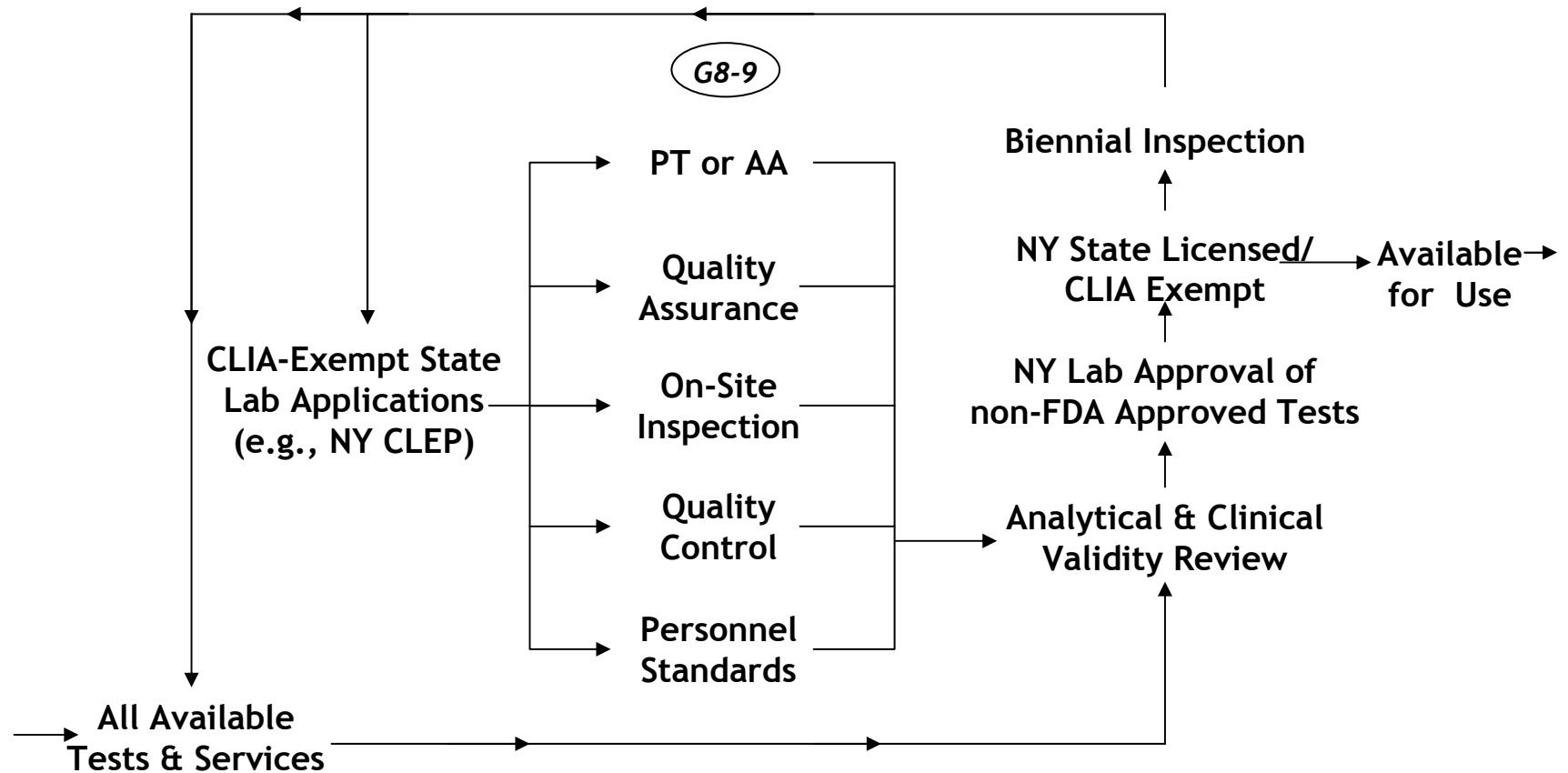
Certification and Inspection of Laboratories



Genetic Testing Oversight Map



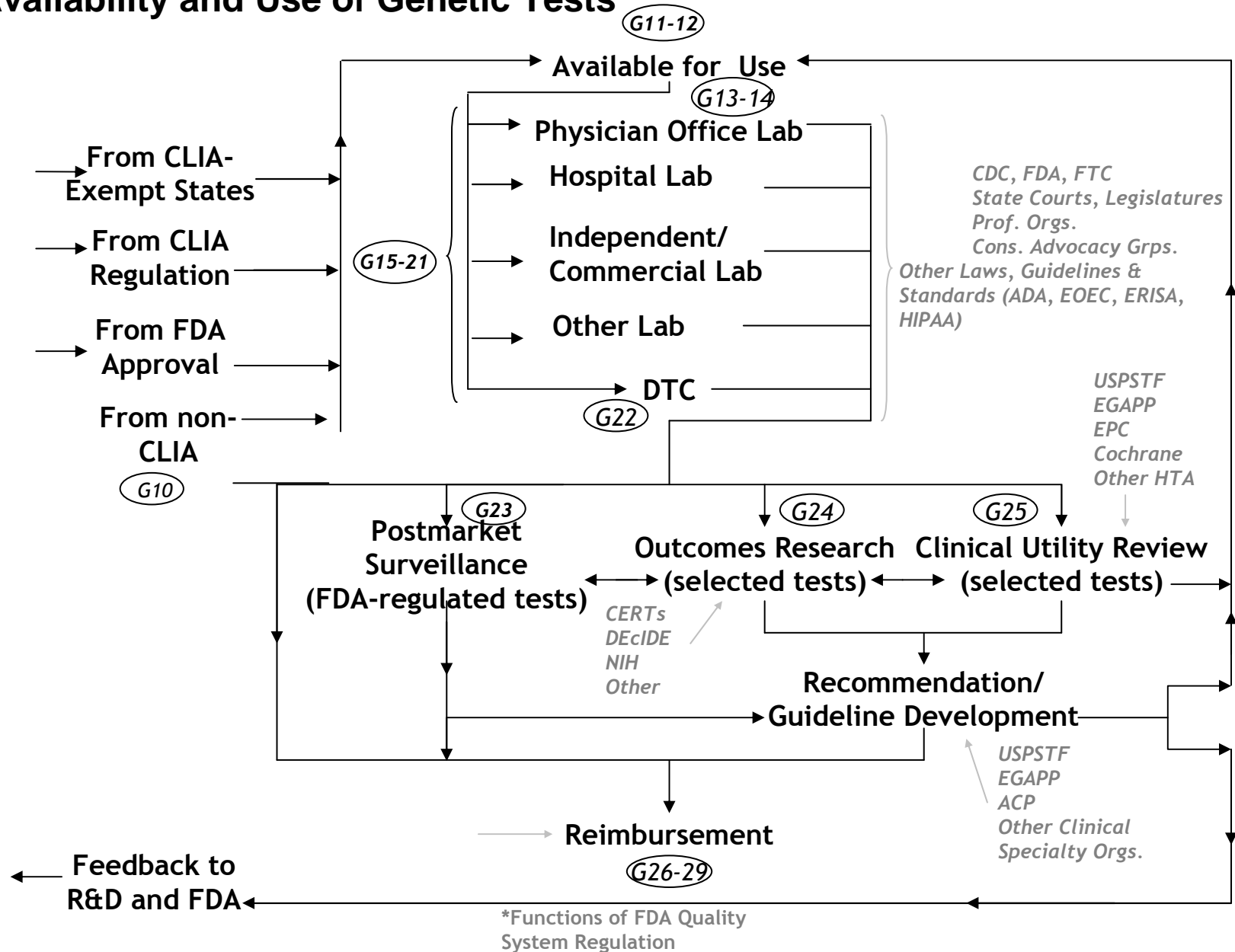
Laboratory Certification in CLIA-Exempt States



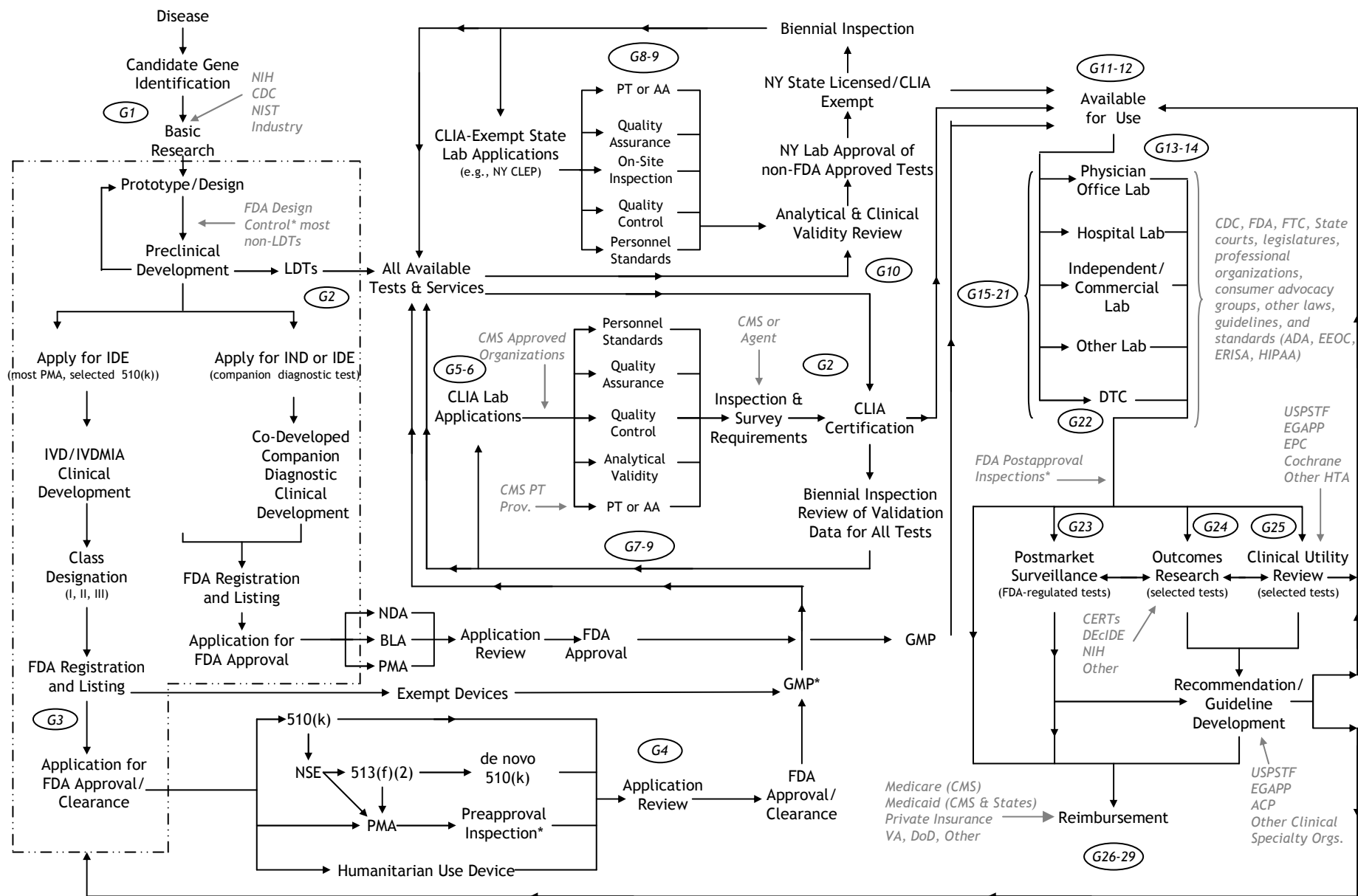
Genetic Testing Oversight Map



Availability and Use of Genetic Tests



U.S. Oversight System for Genetic Testing



Federal Courts

*Functions of FDA Quality System Regulation

RESOURCES

The SACGHS oversight report and map are available at:

http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf