

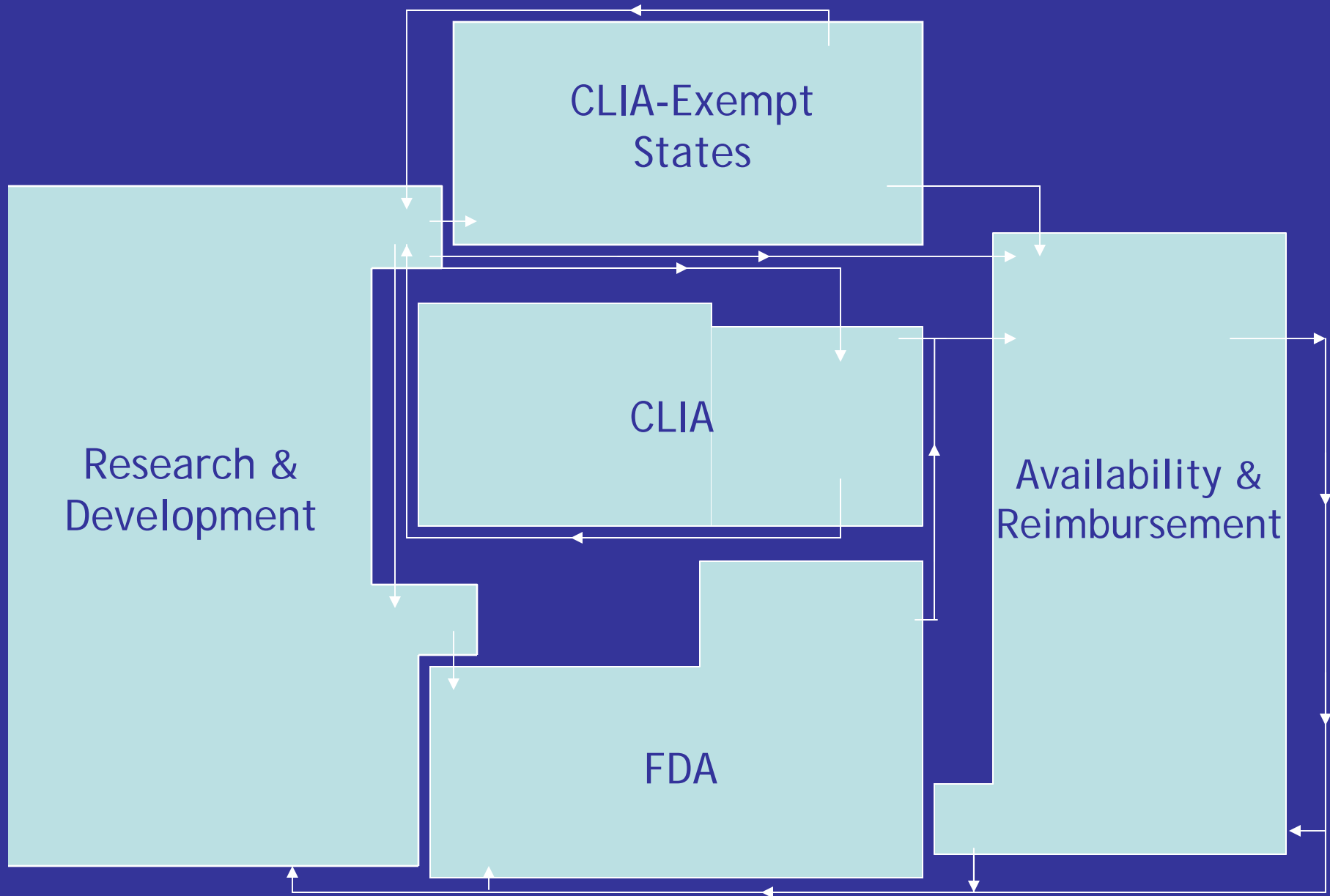
# Comprehensive Map of Genetic Testing Oversight

Presentation to the  
Secretary's Advisory Committee on  
Genetics, Health, and Society

February 12, 2008

*The* LEWIN GROUP  
an **INGENIX**.company

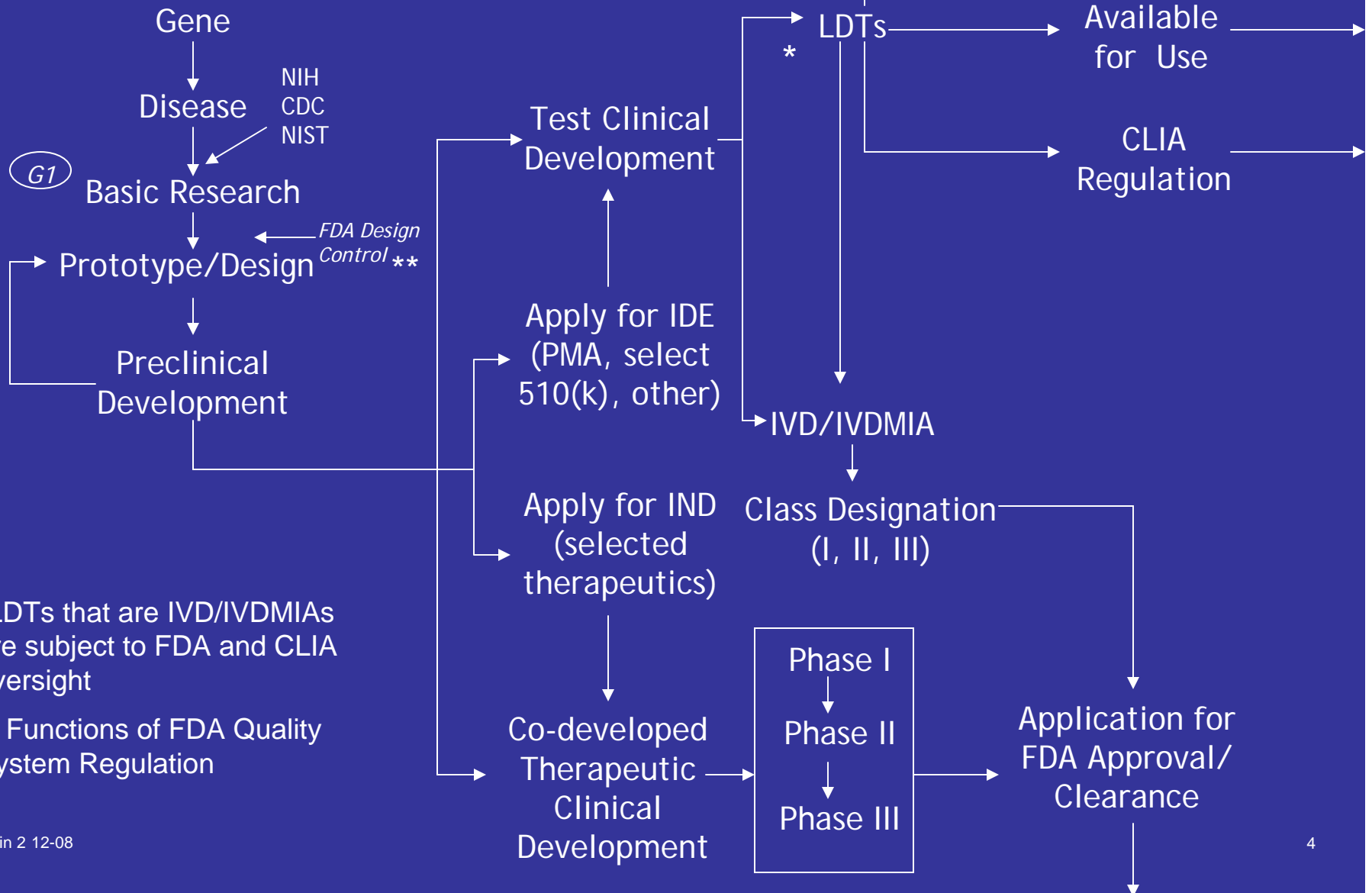
# Genetic Testing Oversight Map



# Genetic Testing Oversight Map



# Research & Development

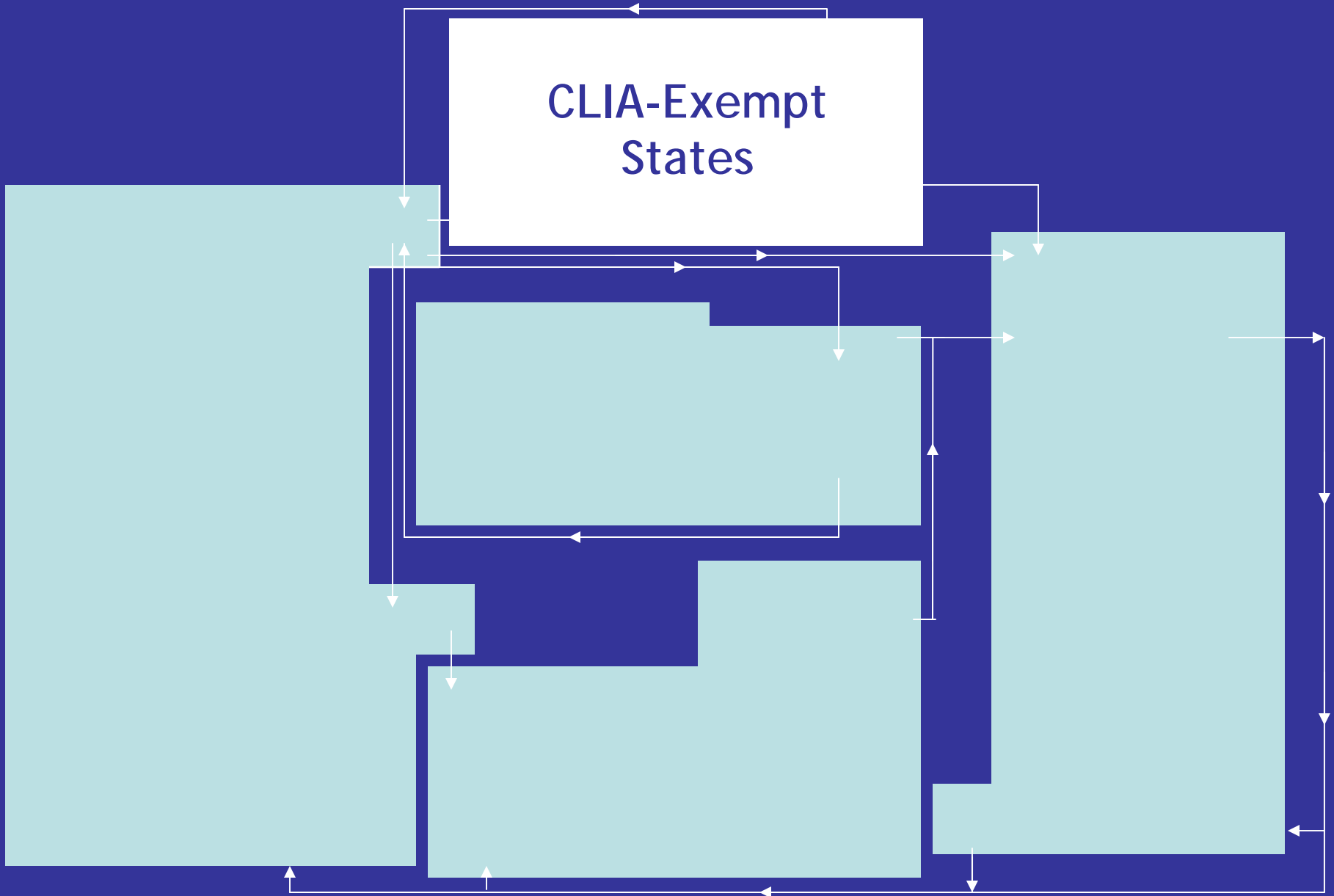


\*LDTs that are IVD/IVDMIAs are subject to FDA and CLIA oversight

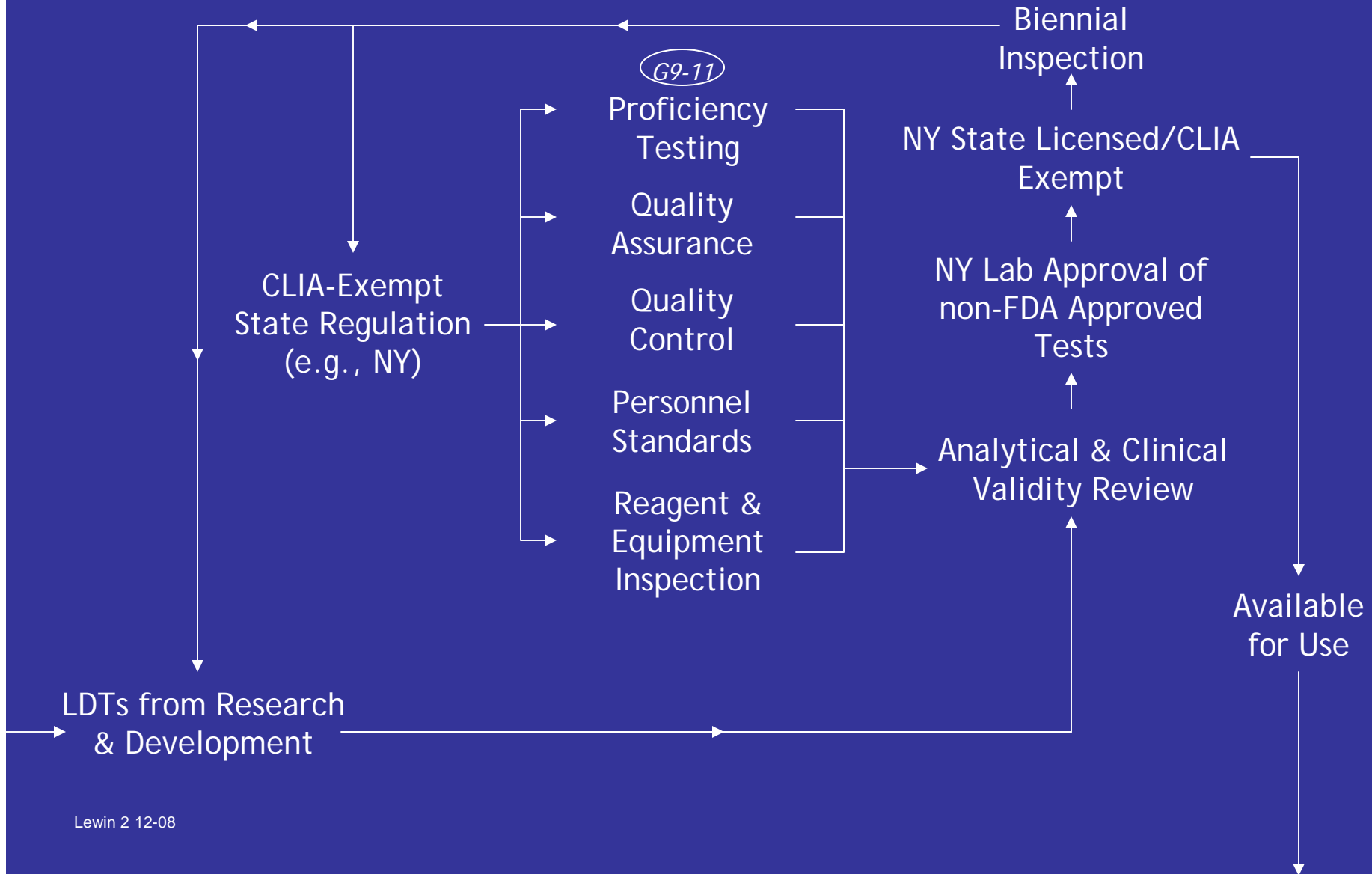
\*\* Functions of FDA Quality System Regulation

# Genetic Testing Oversight Map

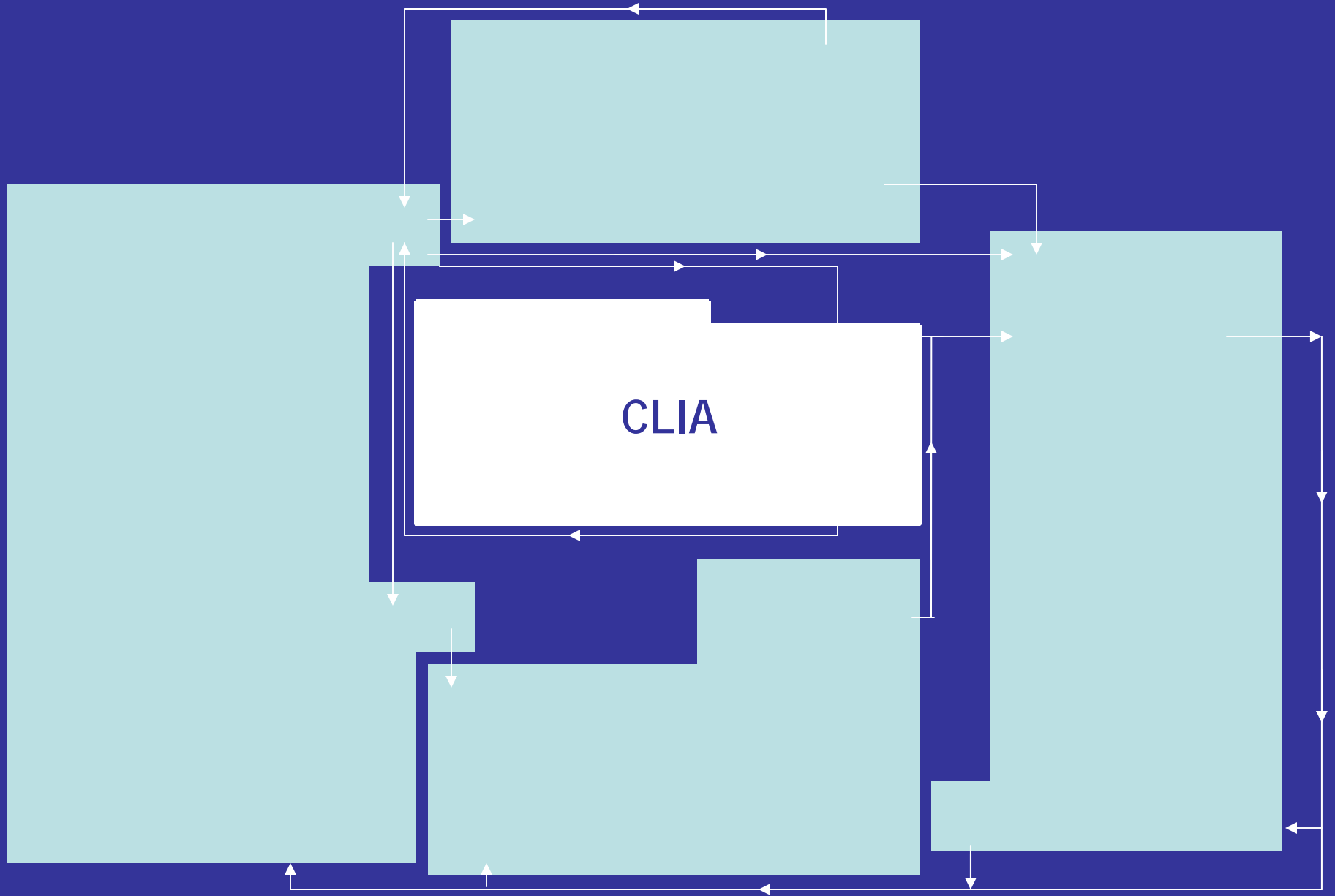
CLIA-Exempt  
States



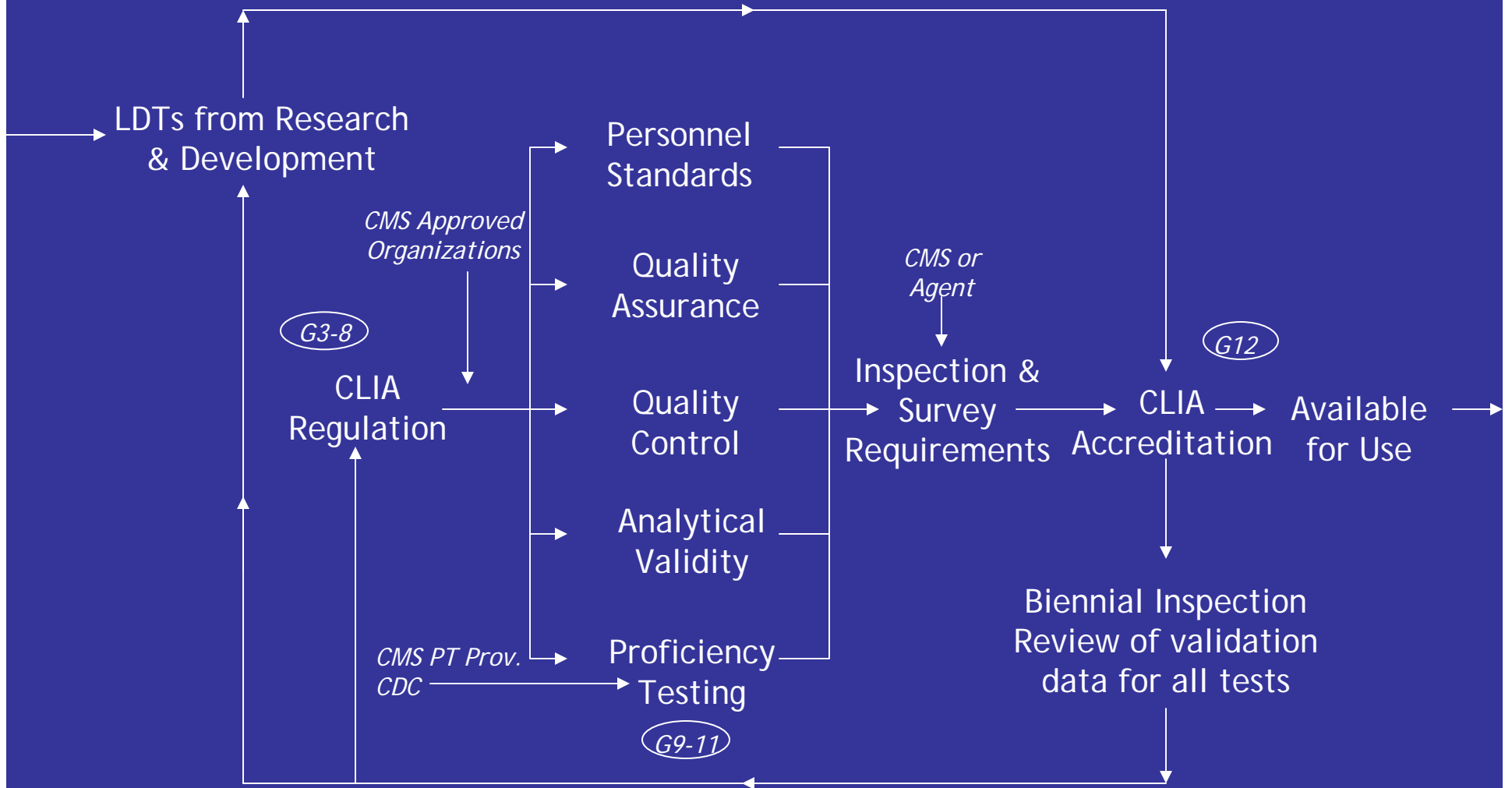
Validation & Certification  
(CLIA-Exempt States)



# Genetic Testing Oversight Map



# Validation & Certification (CLIA)

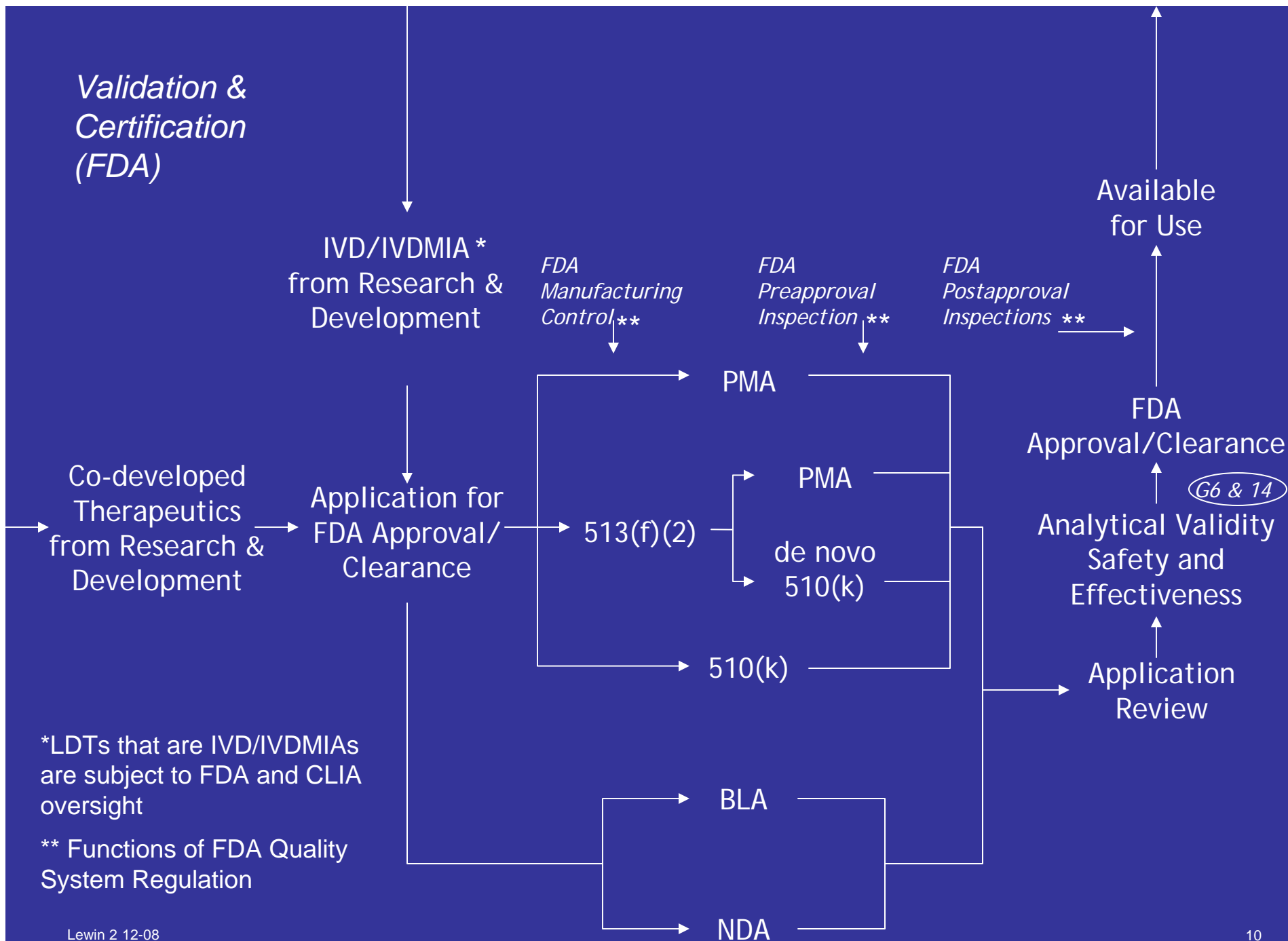




# Genetic Testing Oversight Map



*Validation & Certification (FDA)*



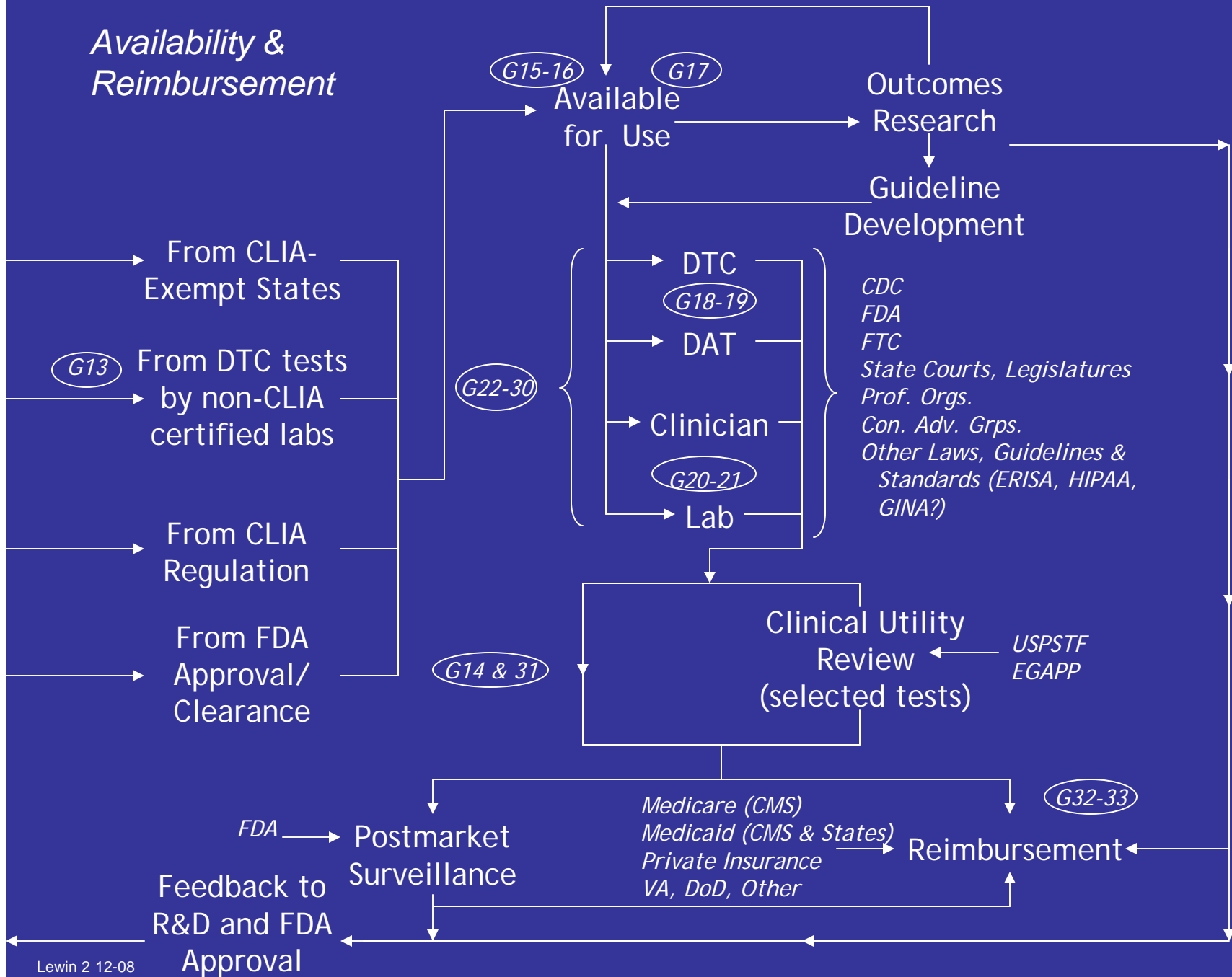
\*LDTs that are IVD/IVDMIA are subject to FDA and CLIA oversight

\*\* Functions of FDA Quality System Regulation

# Genetic Testing Oversight Map



# Availability & Reimbursement



# Genetic Testing Oversight Map

\* LDTs that are IVD/IVDMIA are subject to FDA and CLIA oversight

\*\* Functions of FDA Quality System Regulation

