

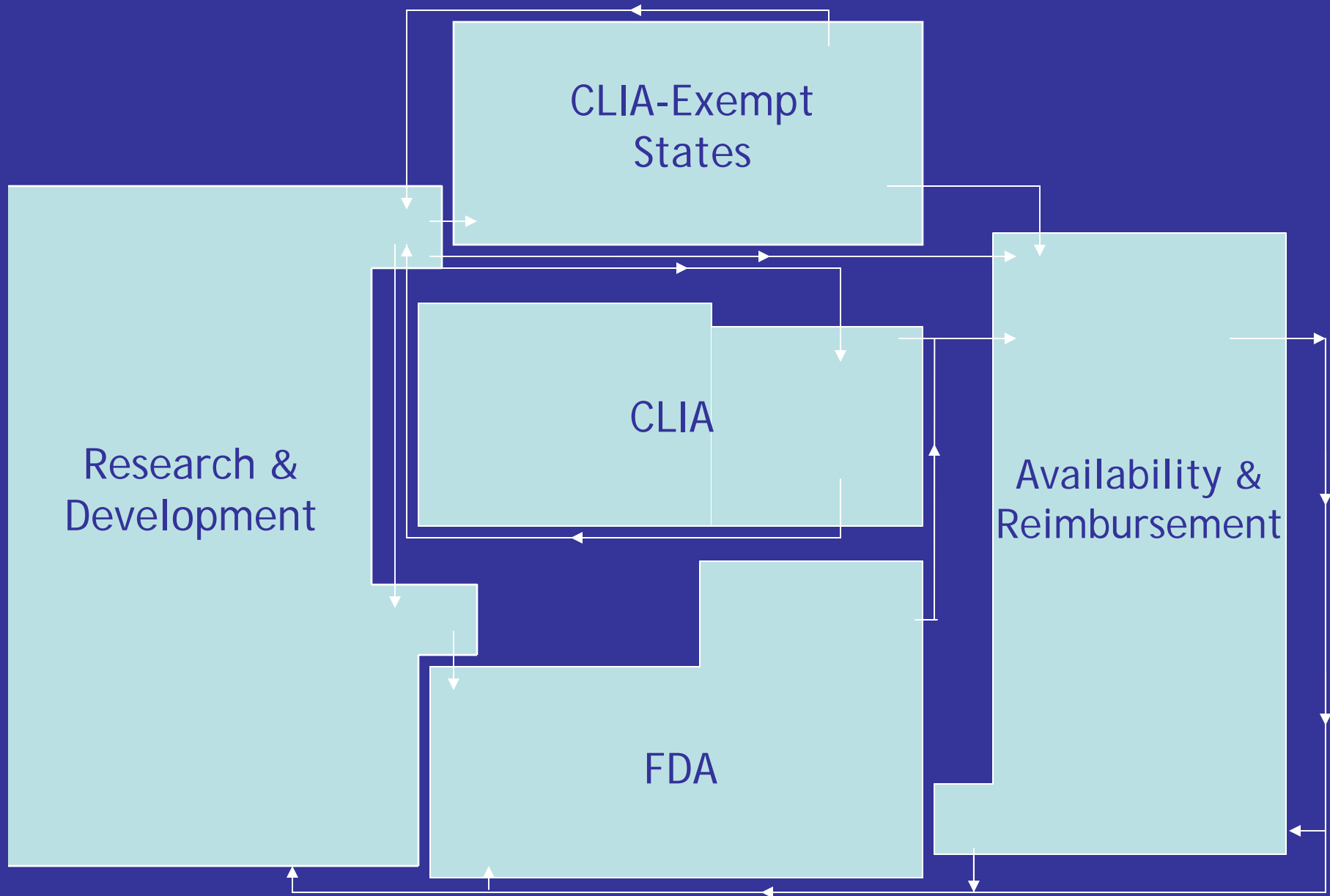
Comprehensive Map of Genetic Testing Oversight

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

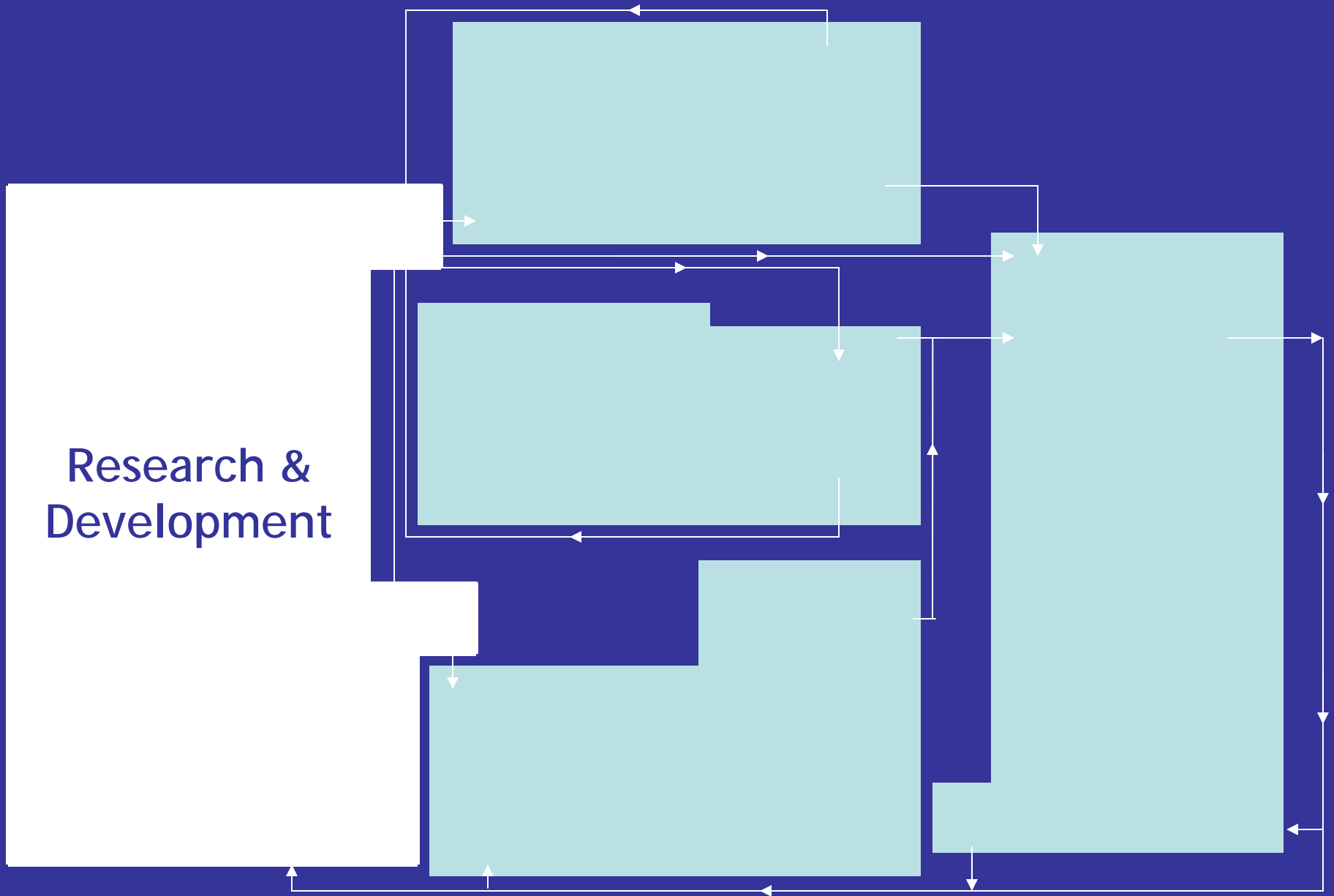
February 12, 2008

The LEWIN GROUP
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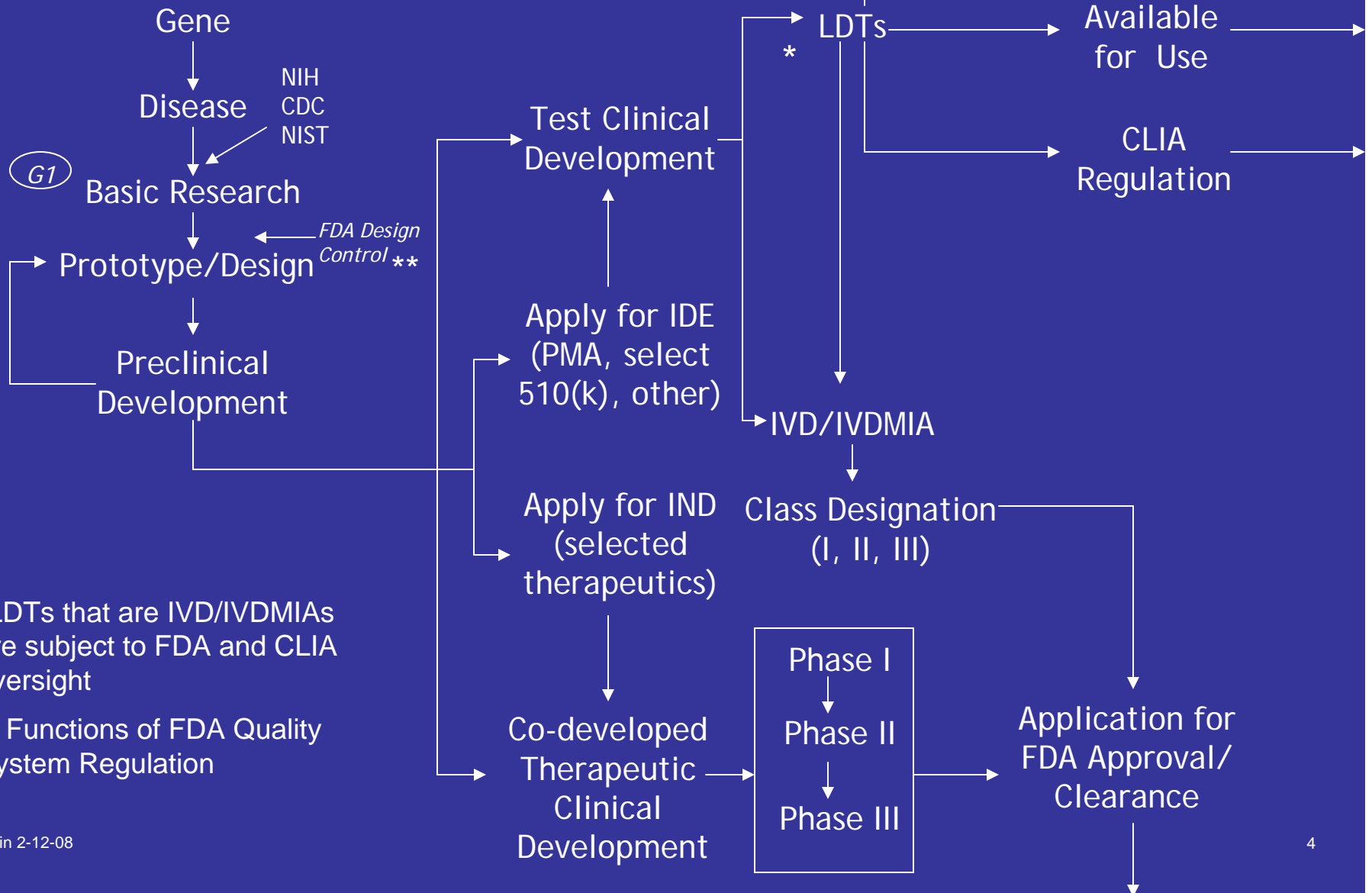
Genetic Testing Oversight Map



Genetic Testing Oversight Map

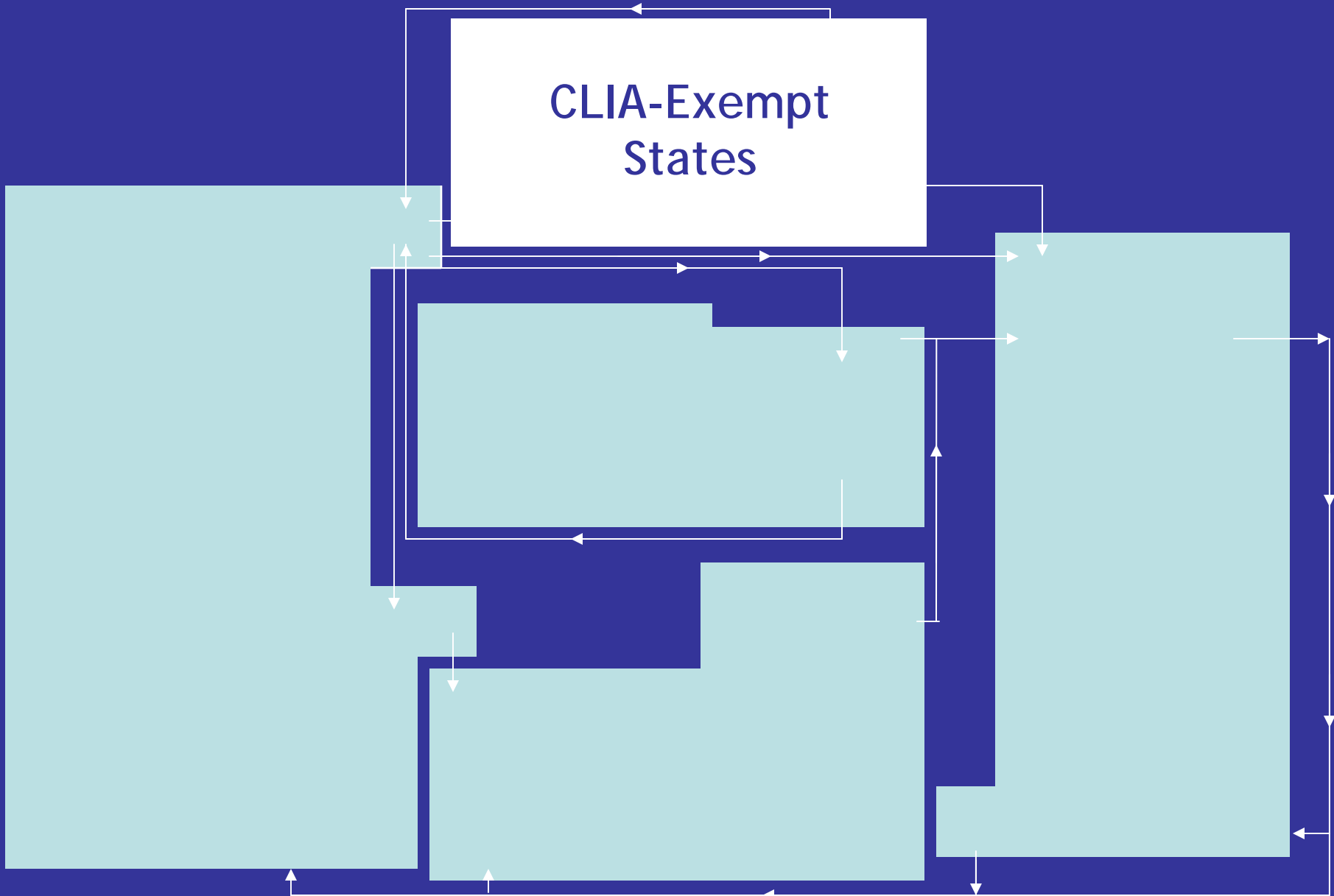


Research & Development

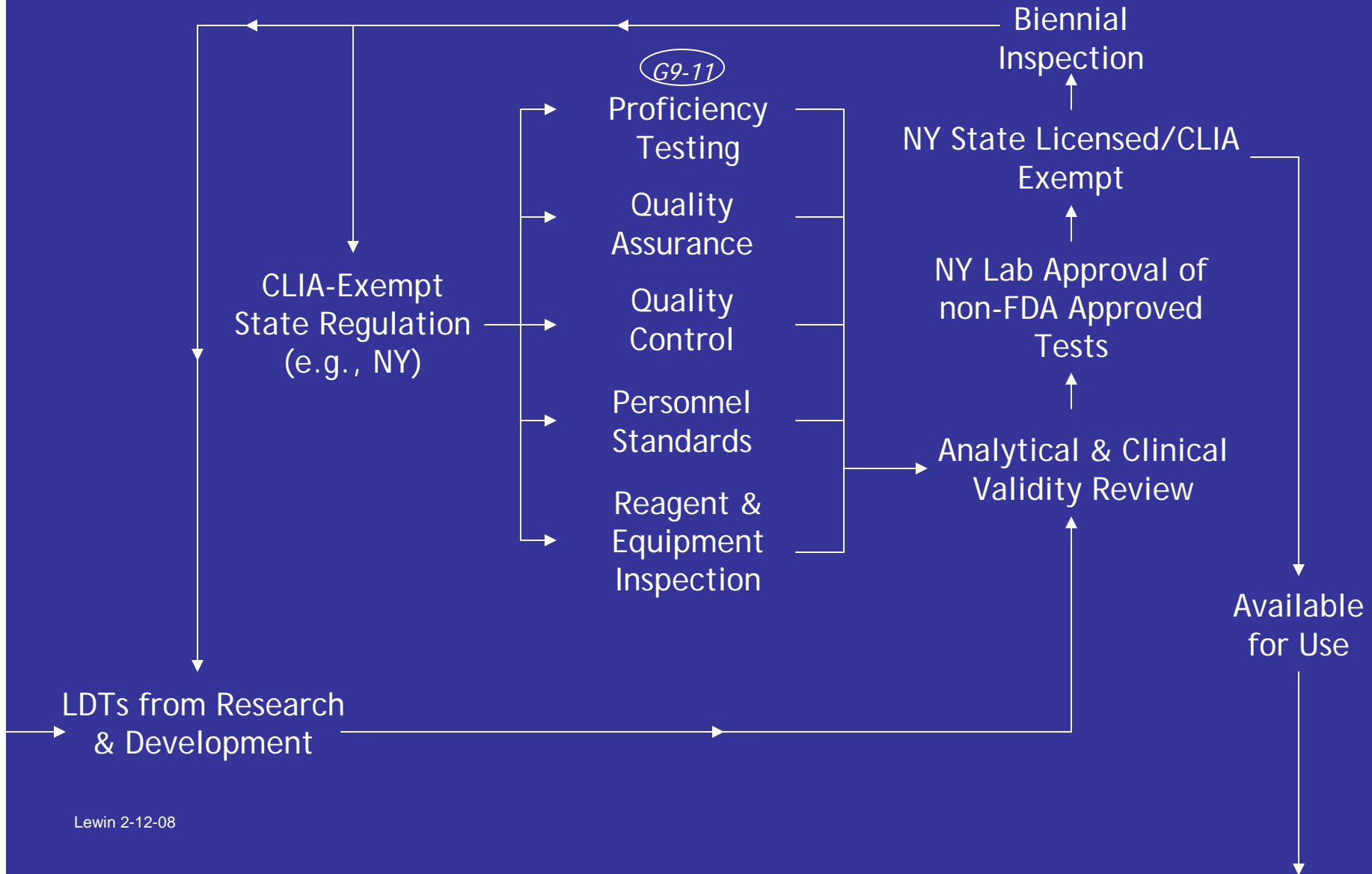


Genetic Testing Oversight Map

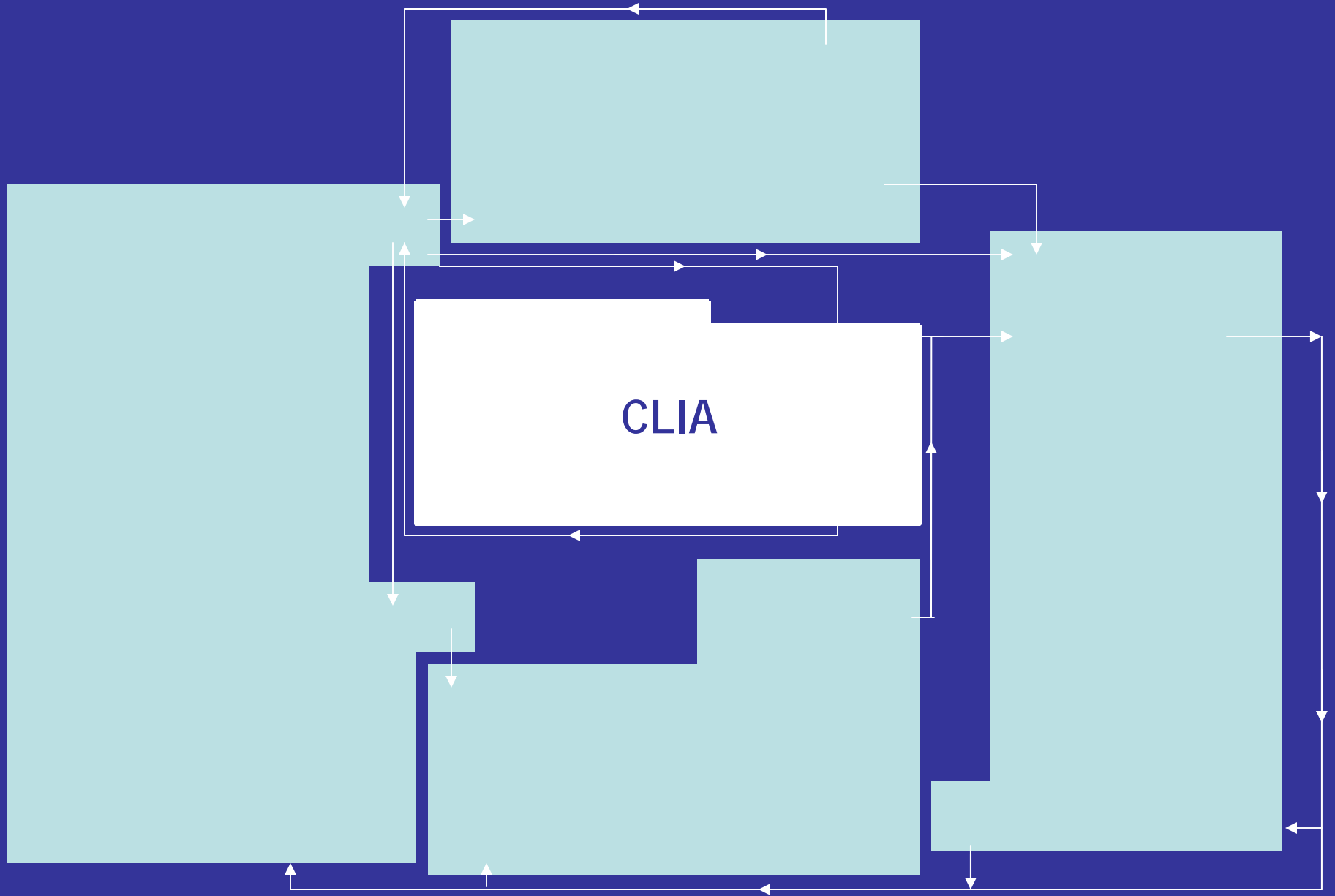
CLIA-Exempt
States



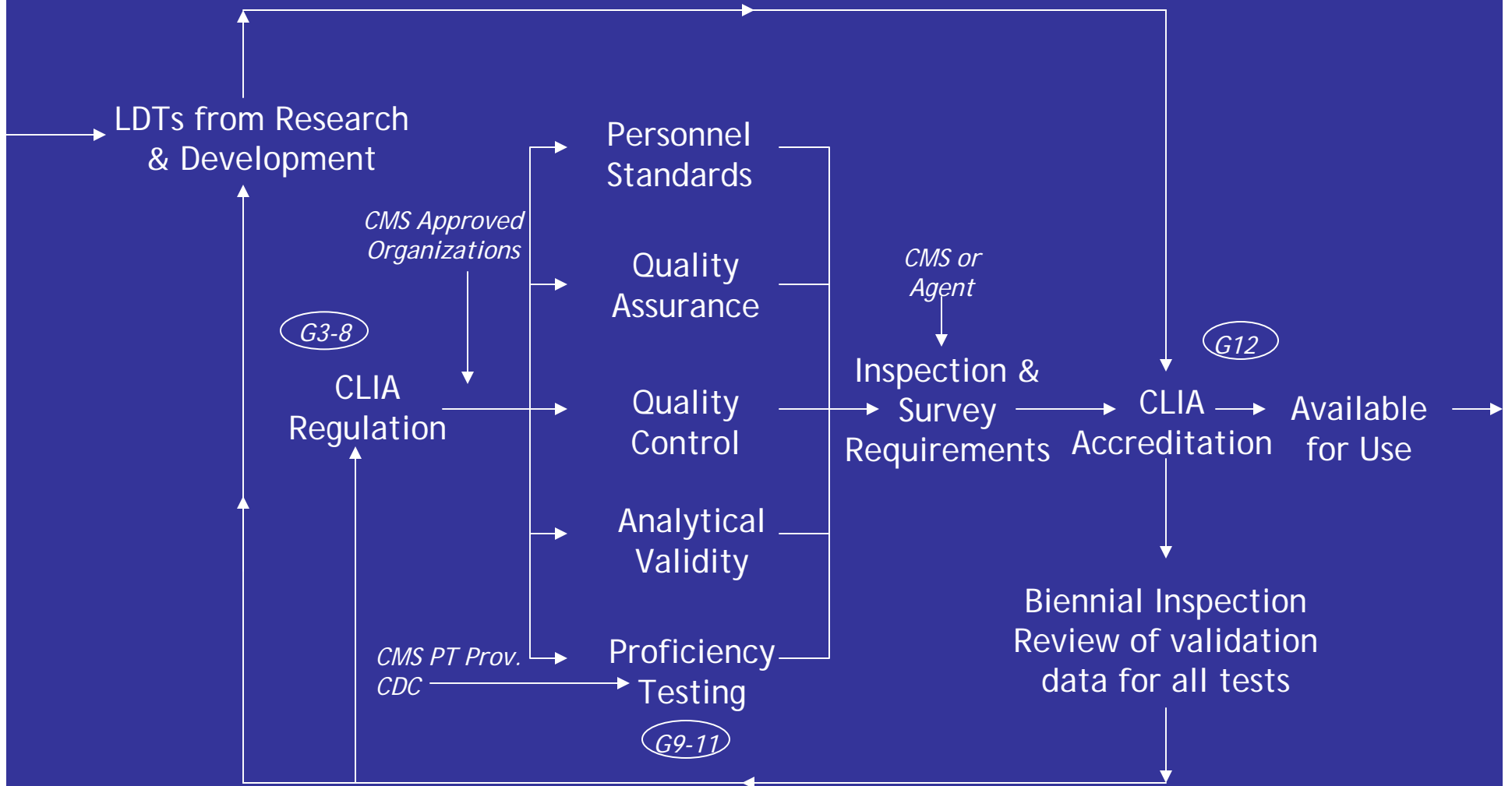
Validation & Certification
(CLIA-Exempt States)



Genetic Testing Oversight Map



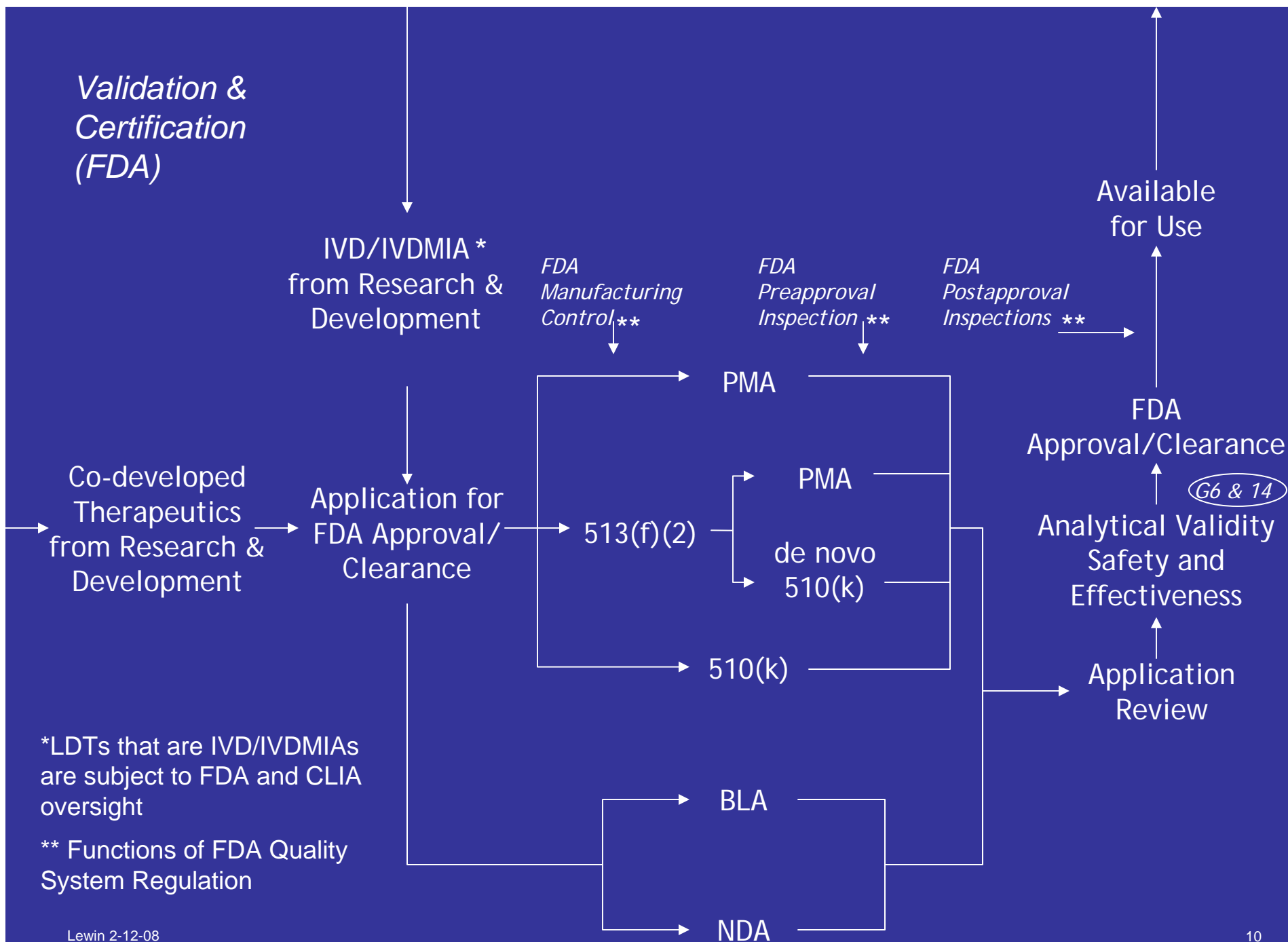
Validation & Certification (CLIA)



Genetic Testing Oversight Map



Validation & Certification (FDA)



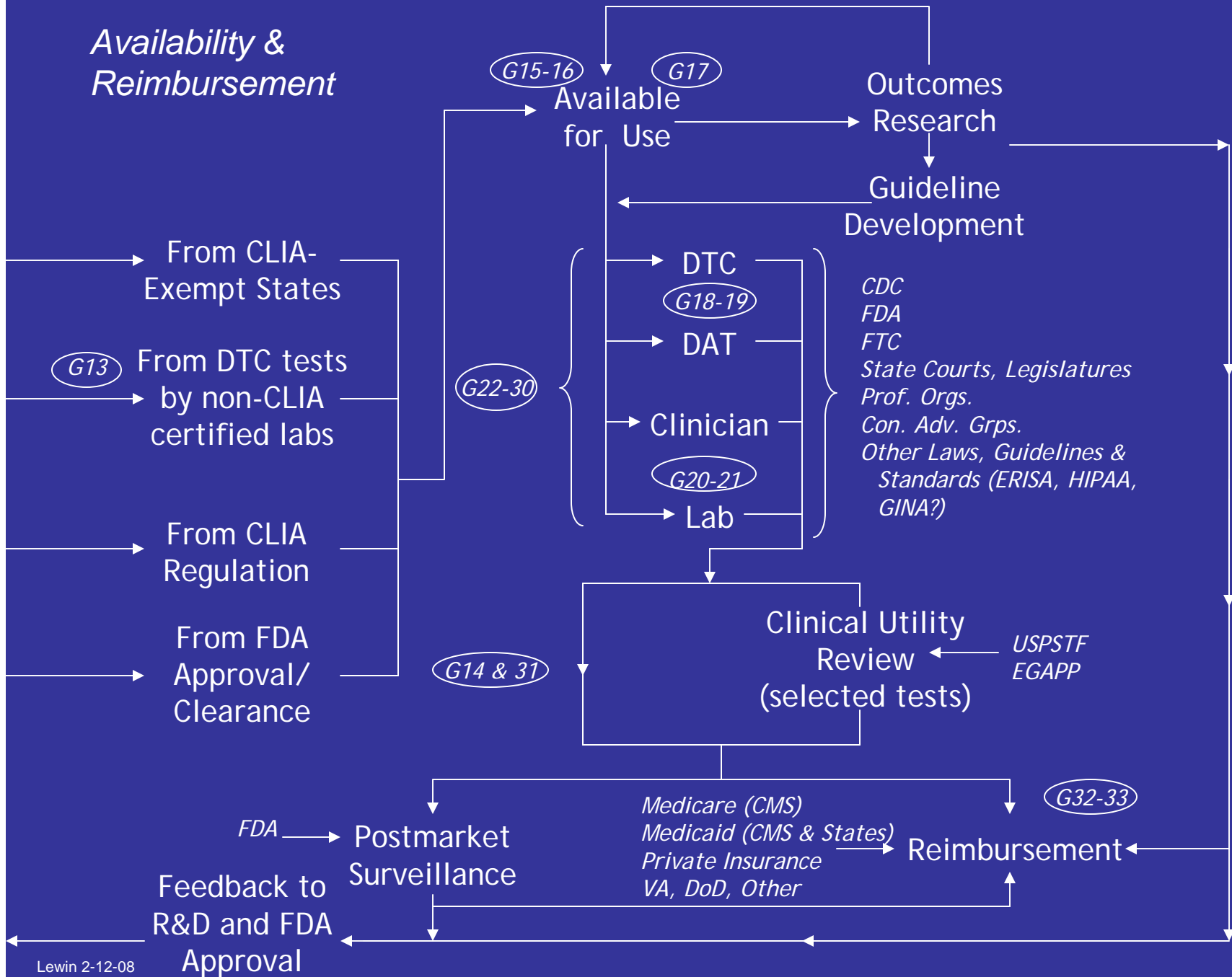
*LDTs that are IVD/IVDMIA are subject to FDA and CLIA oversight

** 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

