FDA Update

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Food and Drug Administration
Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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CLIAC
Atlanta, GA

Summary

- Organizational Update
- Presidential Initiatives
- Approvals and Authorizations
- Guidances
- Workshops and Panels

Organizational Information

- OIR – approx. 305
- New Reviewers
- New Program Support
- Some Changes in Management
- Personalized Medicine/LDT Policy Enhanced

OIR Organizational Update

Alberto Gutierrez, Ph.D.
Director

Donald St. Pierre
Deputy Director, New Product Evaluation

James L. Woods
Deputy Director, Patient Safety and Product Quality

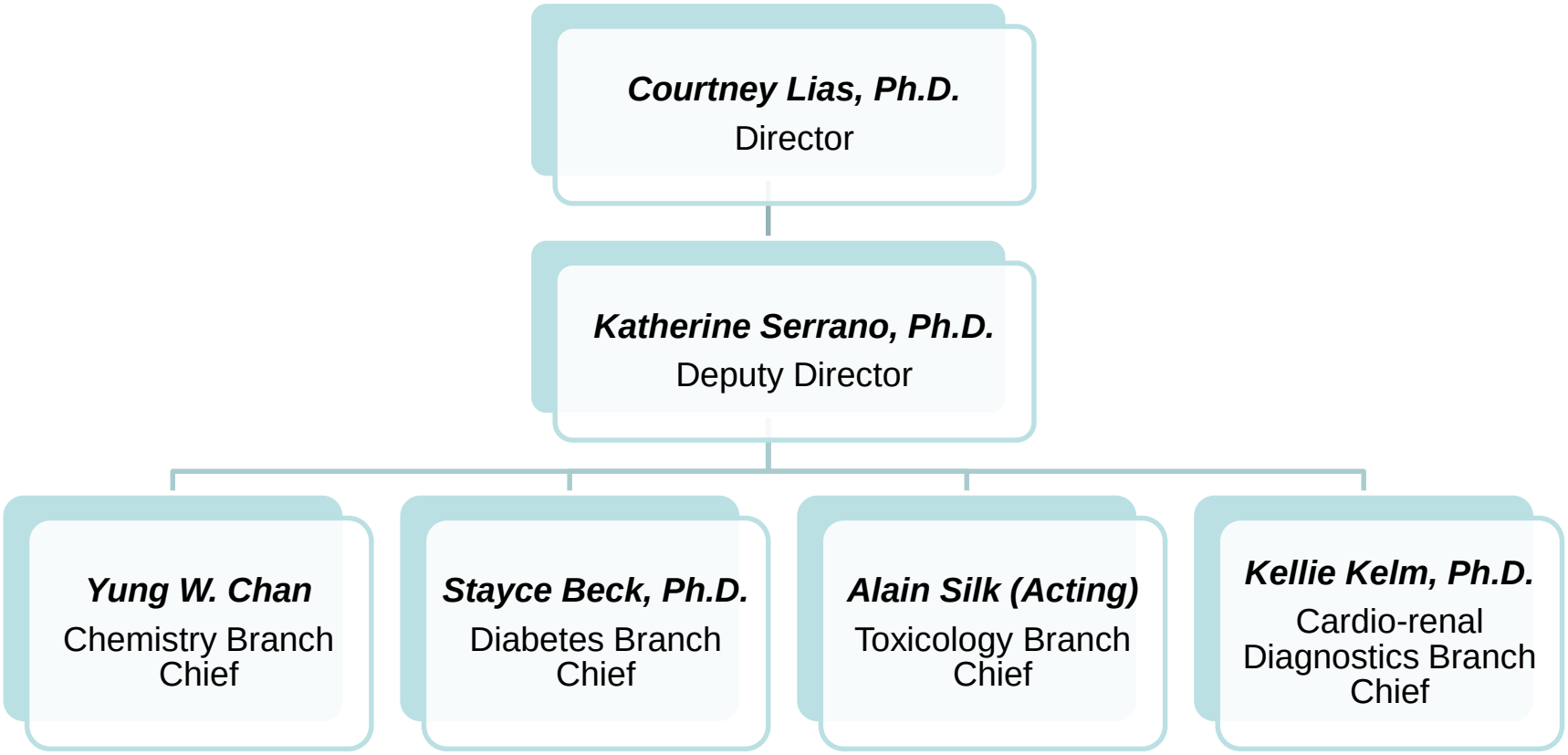
Mary S. Pastel, Sc.D.
Deputy Director, Radiological Health

Elizabeth A. Mansfield, Ph.D.
Deputy Director, Personalized Medicine and Molecular Genetics

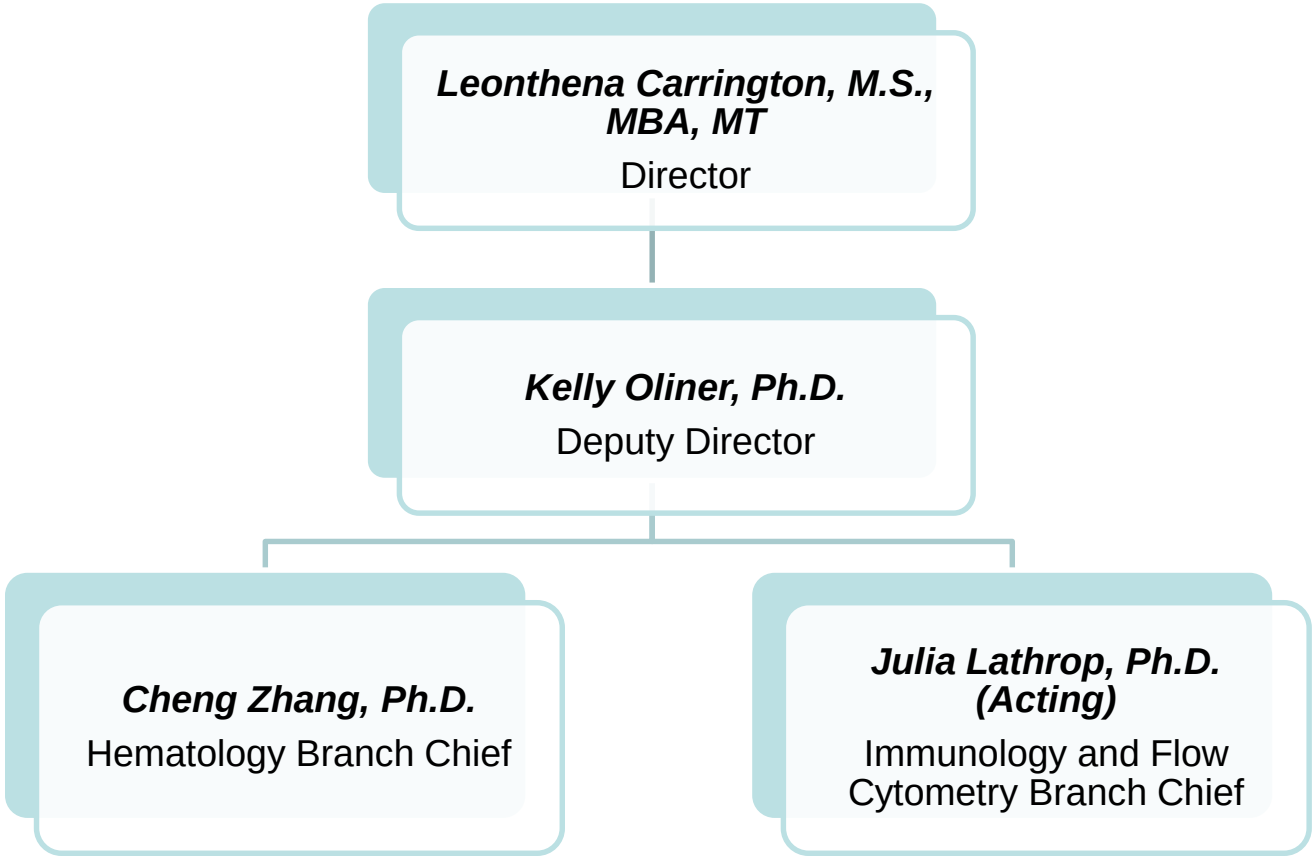
Robert L. Becker, Jr., M.D.
Chief Medical Officer

Donald L. Miller, M.D.
Chief Medical Officer for Radiological Health

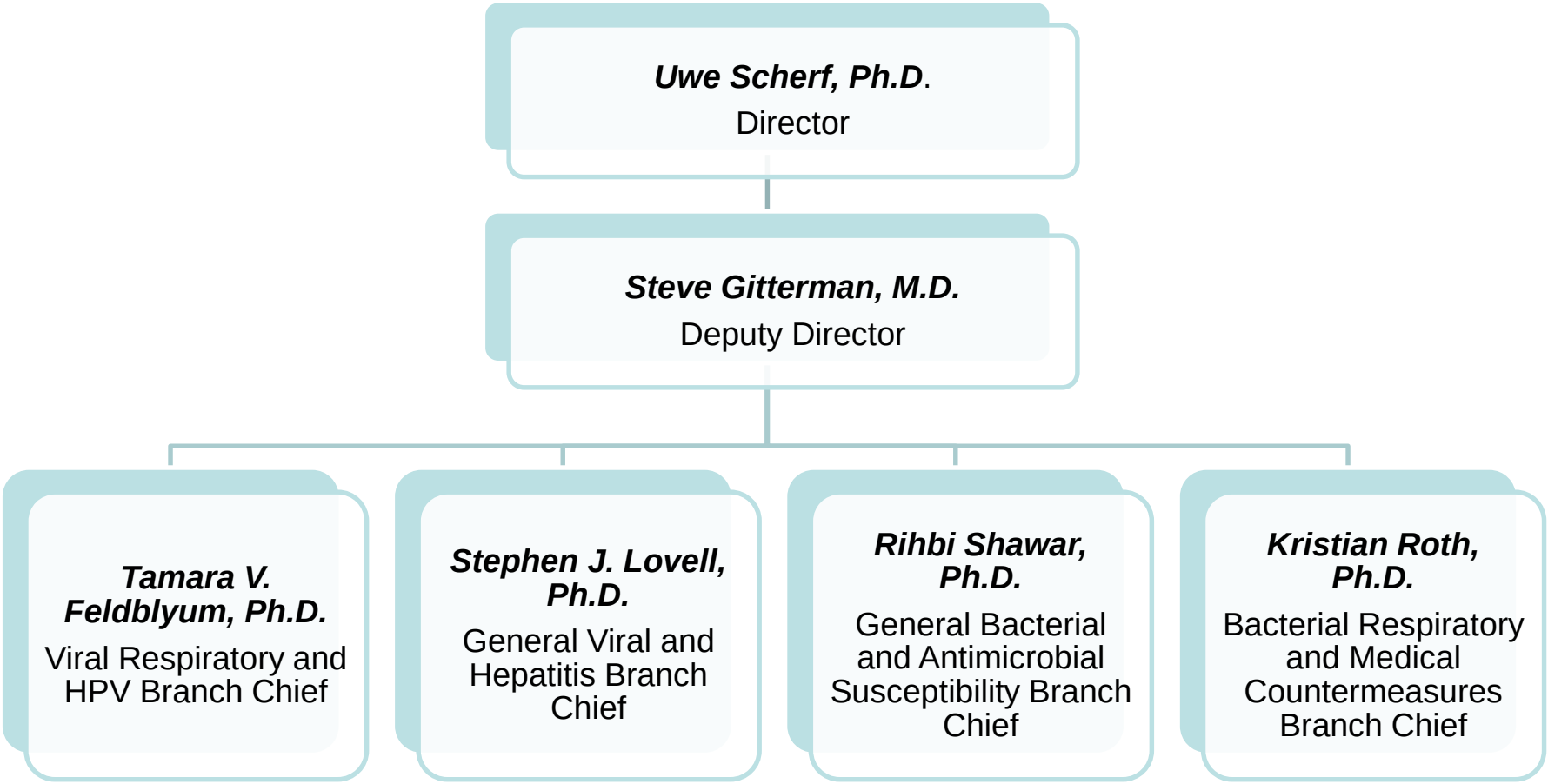
Division of Chemistry and Toxicology Devices



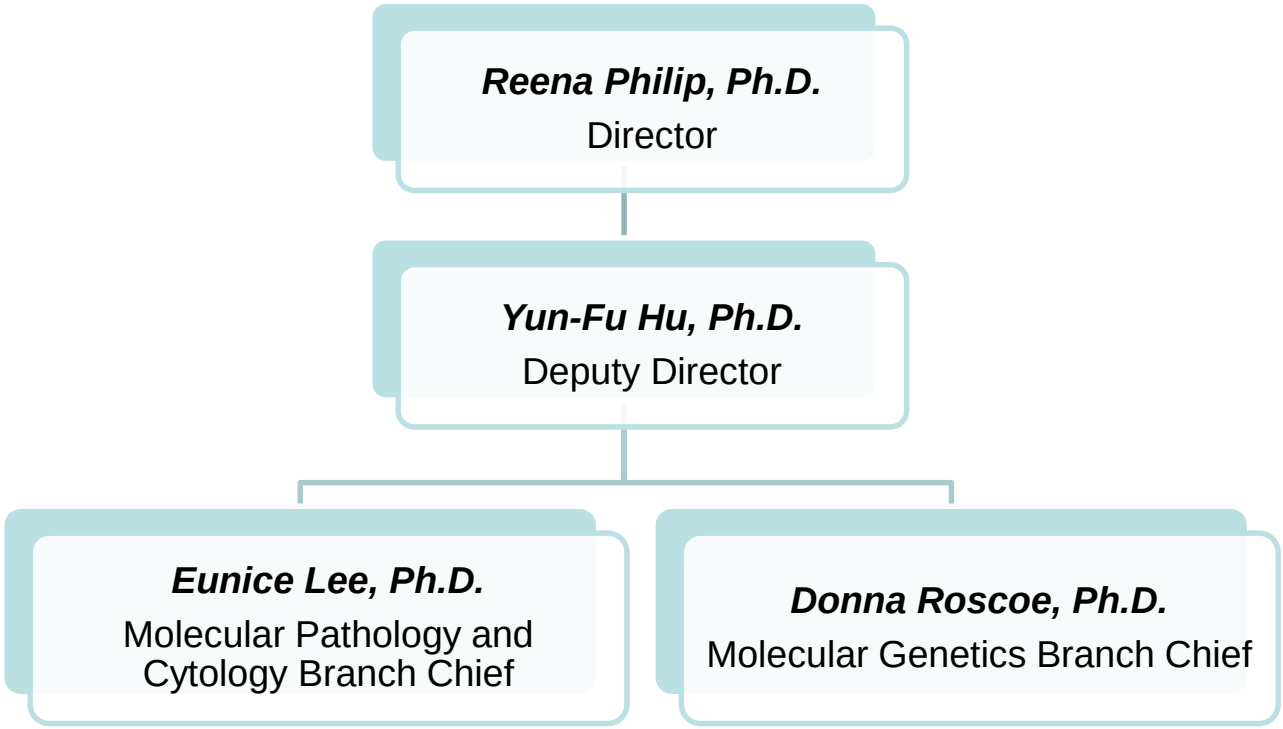
Division of Immunology and Hematology Devices



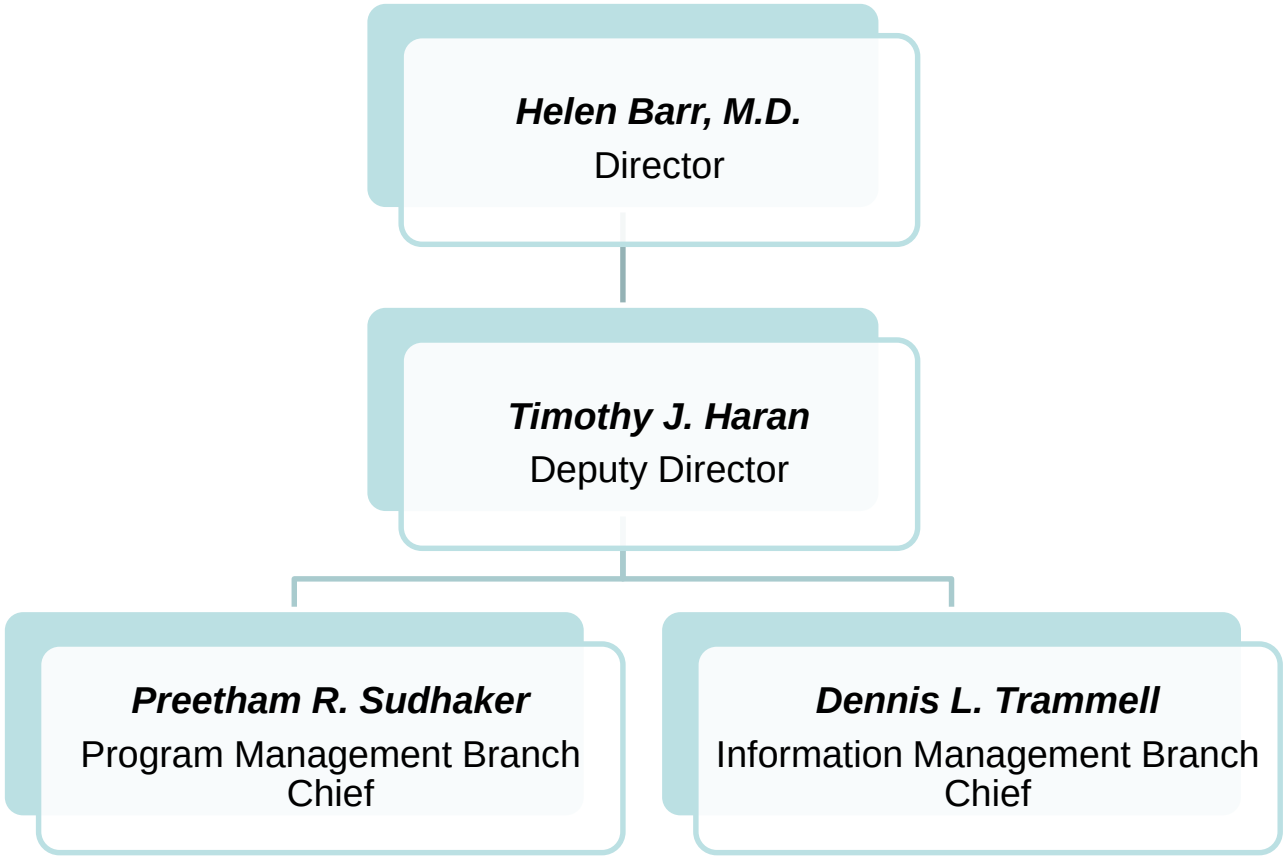
Division of Microbiology Devices



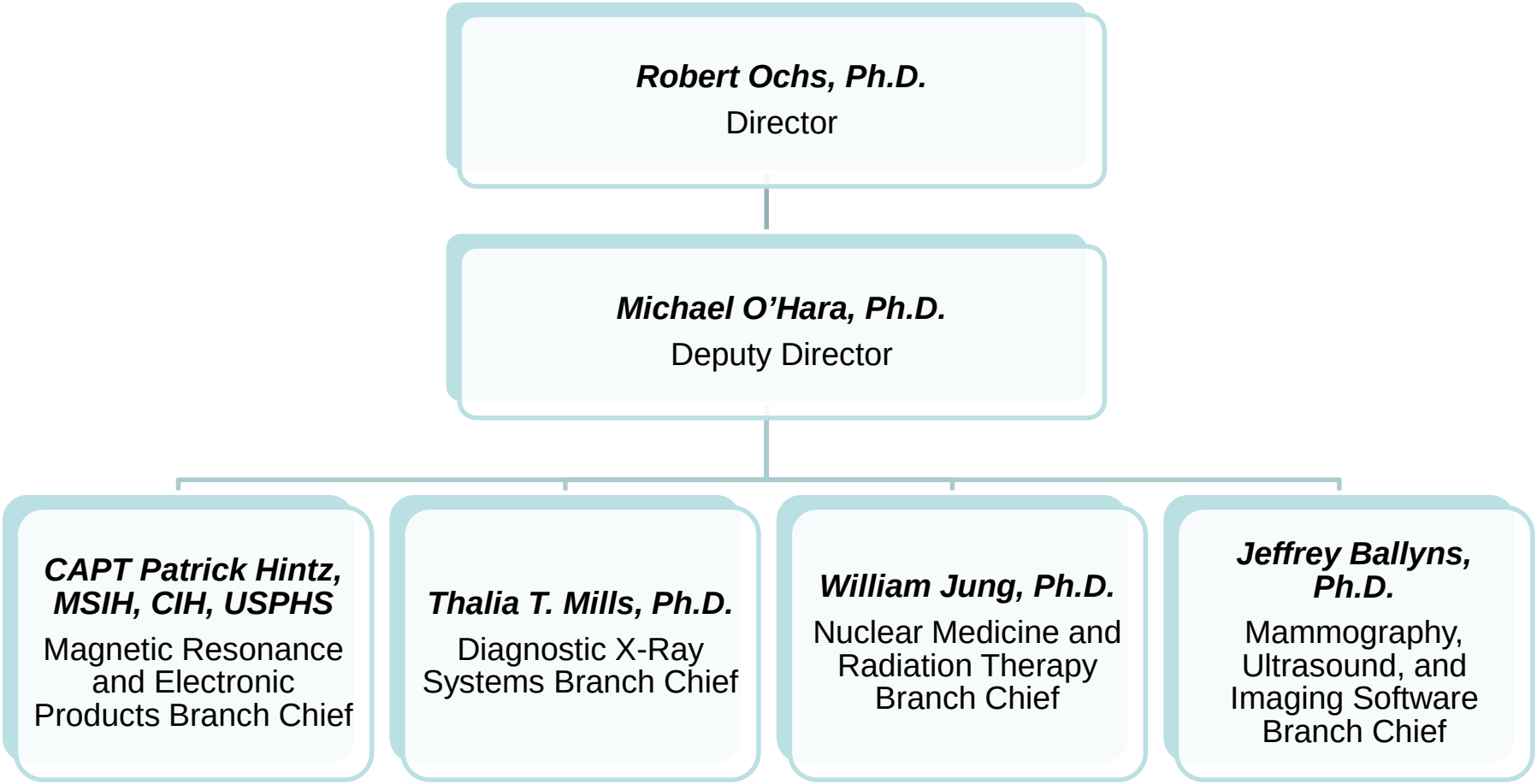
Division of Molecular Genetics and Pathology



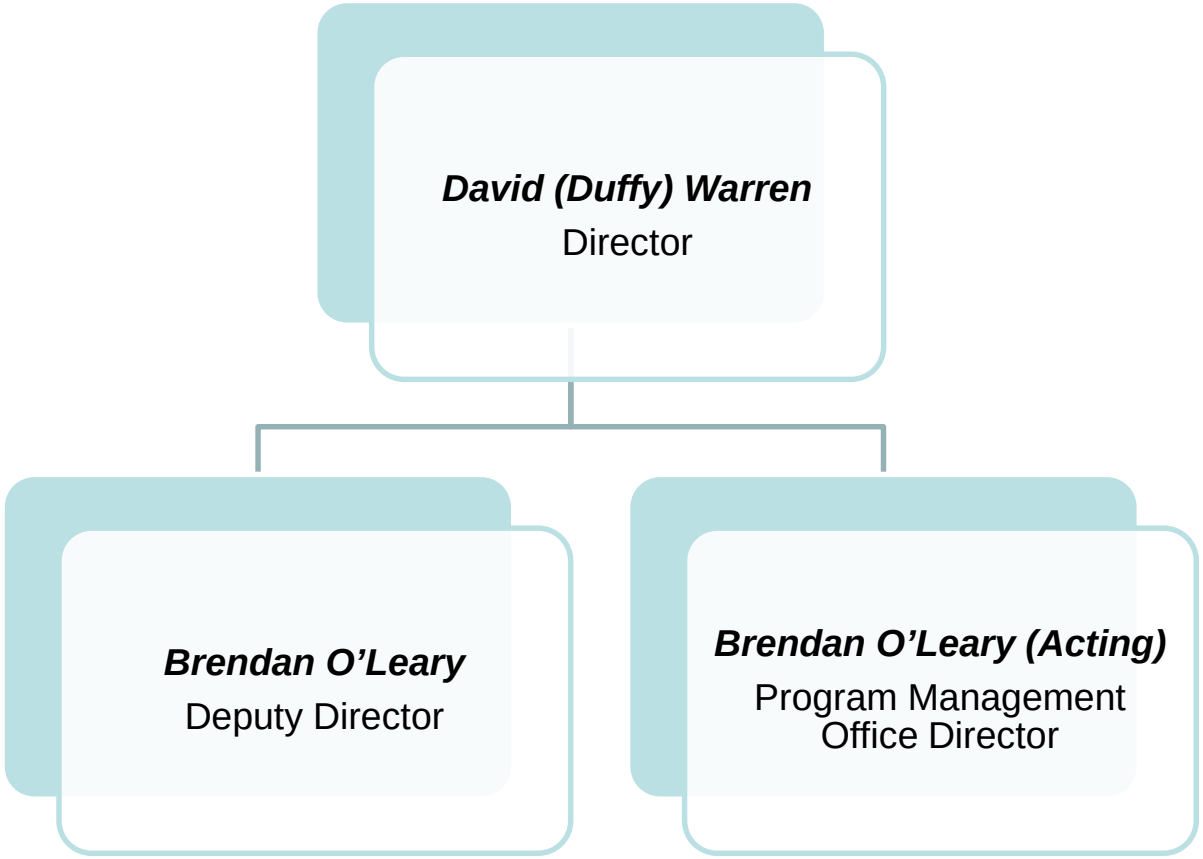
Division of Mammography Quality Standards



Division of Radiological Health



Division of Program Operations and Management



Presidential Initiatives

- National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB)
- The President's Precision Medicine Initiative (PMI)
- US National Cancer Moonshot Initiative

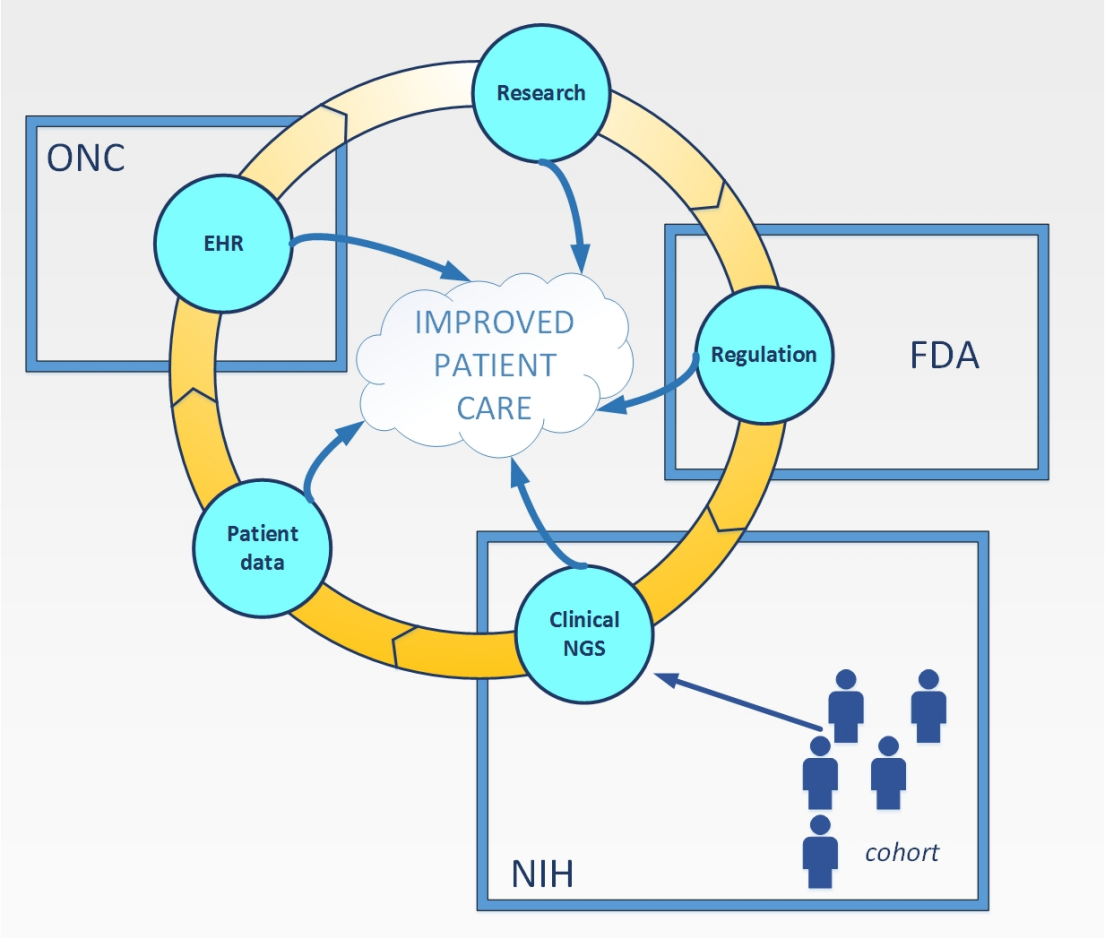
National Action Plan for Combating Antibiotic- Resistant Bacteria (CARB)

- Streamline regulatory processes for updating (breakpoints) and clearing new AST devices
- CDC/FDA developing well characterized, publically available microbial resistance strain panel for anti-microbial resistance Dx and Tx developers
- Develop and maintain sequence data base of resistant pathogens (ARGOS collaboration)

The President's Precision Medicine Initiative (PMI)

To enable a new era of medicine through research and technology that empowers patients, researchers, and providers to work together toward development of individualized treatments.

Precision Medicine Initiative



US National Cancer Moonshot Initiative

- **FDA Virtual Oncology Center of Excellence**
  - This center will expedite the development of novel combination products and support an integrated approach in:
    - evaluating products for the prevention, screening, diagnosis, and treatment of cancer;
    - supporting the continued development of companion diagnostic tests, and the use of combinations of drugs, biologics and devices to treat cancer; and
    - developing and promoting the use of methods created through the science of precision medicine.

PMA Approvals IVDs

Dako's PD-L1 IHC 28-8 pharmDx

- previously approved as a complementary diagnostic for testing tumor specimens from patients with non-small cell lung cancer.
- this approval expands the indication to tumor specimens from patients with melanoma.

PMA Approvals IVDs

Paradigm REAL-Time Revel insulin pump

- for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Enlite Sensor

- for use with the Paradigm REAL-Time Revel insulin pump systems to continuously monitor glucose levels in persons with diabetes.

De Novo Classifications

B.R.A.H.M.S PCT sensitive KRYPTOR

- an immunofluorescent assay using Time-Resolved Amplified Cryptate Emission (TRACE) technology to determine the concentration of PCT (procalcitonin) in human serum and EDTA or heparin plasma.
- Procalcitonin (PCT) is a biomarker associated with the inflammatory response to bacterial infection that aids in the risk assessment of critically ill patients on their first day of Intensive Care Unit (ICU) admission for progression to severe sepsis and septic shock.

CLIA Waivers by Application

Cepheid Gene Xpert Xpress System {Xpert Flu+RSV Xpress Assay}

- an automated, multiplex real-time, reverse transcriptase polymerase chain reaction (RT-PCR) assay intended for the in vitro qualitative detection and differentiation of influenza A, influenza B, and respiratory syncytial virus (RSV) viral RNA.
- 2nd Dual 510(k) and CLIA Waiver by Application Approved

Emergency Use Authorizations (2016)

Zika Virus Emergency Use Authorizations

- CDC MAC-ELISA (February 26, 2016)
  - A screening test that can detect antibodies in blood beginning four to five days after onset of symptoms
- CDC Trioplex Real-time RT-PCR Assay (March 17, 2016)
  - allows doctors to tell if an individual is currently infected with chikungunya, dengue, or Zika using one test, instead of having to perform three separate tests to determine which infection one might have

OraQuick® Ebola Rapid Antigen Test (March 4, 2016)

- for use with cadaveric oral fluid from individuals with epidemiological risk factors

Final Guidances

- Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays
- Applying Human Factors and Usability Engineering to Medical Devices
- eCopy Program for Medical Device Submissions

Draft Guidances

- Display Devices for Diagnostic Radiology
- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices
- Postmarket Management of Cybersecurity in Medical Devices
- Unique Device Identification: Convenience Kits
- Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals")

Laboratory Developed Tests (LDTs)

- FDA is working on developing final LDT guidance:
  - Reviewing and synthesizing public comments
  - Modifying guidance documents based on public input received
  - Providing a robust response to comments
- FDA intends to issue final guidance in 2016
- Ongoing education and training will be provided

Notable Meetings

- Public Workshop - Point of Care Prothrombin Time/International Normalized Ratio Devices for Monitoring Warfarin Therapy, March 18, 2016 (Rescheduled)
- CDRH Industry Basics Workshop - Unique Device Identification (UDI) Part II, Submitting Information to GUDID, March 10th, 2016
- Public Workshop - Advancing the Development of Biomarkers in Traumatic Brain Injury, March 3, 2016

Notable Meetings Cont.

- Public Workshop - Patient and Medical Professional Perspectives on the Return of Genetic Test Results, March 2, 2016
- Public Workshop - Next Generation Sequencing-Based Oncology Panels, February 25, 2016
- CDRH Industry Basics Workshop - Unique Device Identification (UDI), January 27, 2016
- Public Workshop - Moving Forward: Collaborative Approaches to Medical Device Cybersecurity, January 20-21, 2016

Thanks