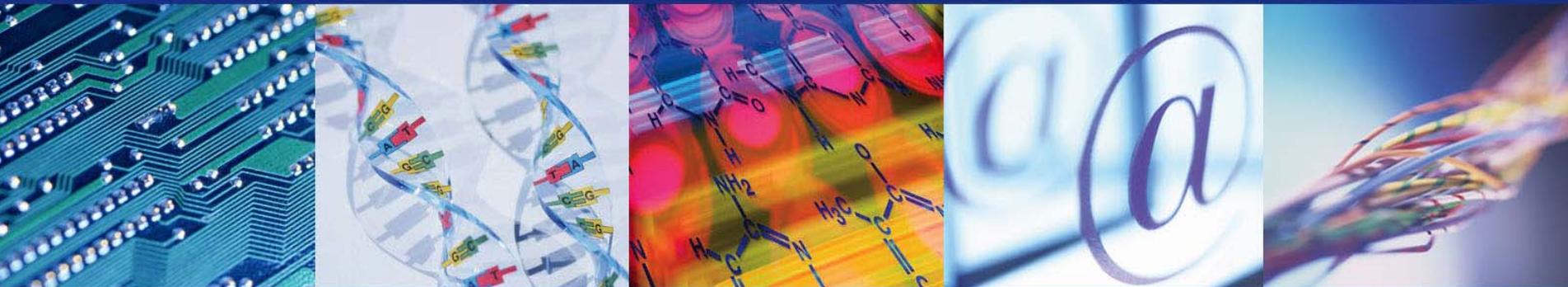




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FDA's Draft Guidance on IVDMIAs:

**Enhancing the Critical Path or Deterring Investment
in Innovative Diagnostics?**

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- **Patient interests are paramount**
- **Billions of dollars invested, hundreds of millions of patients served**
- **Valued partnership with the FDA to continue to reduce human suffering and improve patient outcomes**

- **The diagnostic and laboratory industries are on the cusp of dramatically improving medicine and healthcare**
- **New, innovative diagnostic technologies will:**
 - Expand the scope of molecular diagnostics
 - Make personalized medicine a reality
 - Lead to better health outcomes
 - Lower the cost of healthcare
 - Reduce adverse events

- **Many of the companies and laboratories developing the innovative diagnostics with the most promise are small and entrepreneurial**
- **In order to make the benefits to healthcare a reality, these small companies and laboratories need access to capital**

- **Funding for diagnostics research has historically been much lower than funding for drug research and for other devices**
- **Funding for diagnostics continues to lag behind that for drugs and other devices**
- **If implemented in its current form, the draft guidance document on IVDMIAs will lead to even less funding of diagnostics**

- **The draft guidance creates tremendous ambiguity and regulatory uncertainty**
 - It is not clear what types of laboratory services will be subject to regulation by FDA as IVDMIA
 - If a laboratory service is subject to regulation by FDA as an IVDMIA, it is not clear what the level of regulation will be
 - FDA has not clearly defined an IVDMIA and has not laid out a regulatory path

- **Under the draft guidance, it is also not clear:**
 - Whether and how laboratories will comply with both FDA and CLIA requirements
 - How products or services deemed to be IVDMIAAs will be labeled
 - What the costs of compliance with the draft guidance will be; these cannot be calculated with any certainty

- **To attract investors, companies and laboratories need to know:**
 - Whether their product or service is going to be regulated by FDA
 - The nature of the regulation
 - The costs of compliance with the regulation
- **Under the draft guidance on IVDMIAs, companies do not know this**

- **Investors need to evaluate the risks and benefits of a potential investment**
- **Ambiguous regulatory schemes and regulatory uncertainty do not enable this evaluation**
 - If investors cannot assess whether a product will be regulated by FDA, or what the level of regulation will be, investments will be dampened

- **The ambiguities and regulatory uncertainty under the draft guidance will deter investments in innovative diagnostics**
- **If the draft guidance is implemented, investors looking for opportunities in technology or healthcare will look to alternative opportunities**

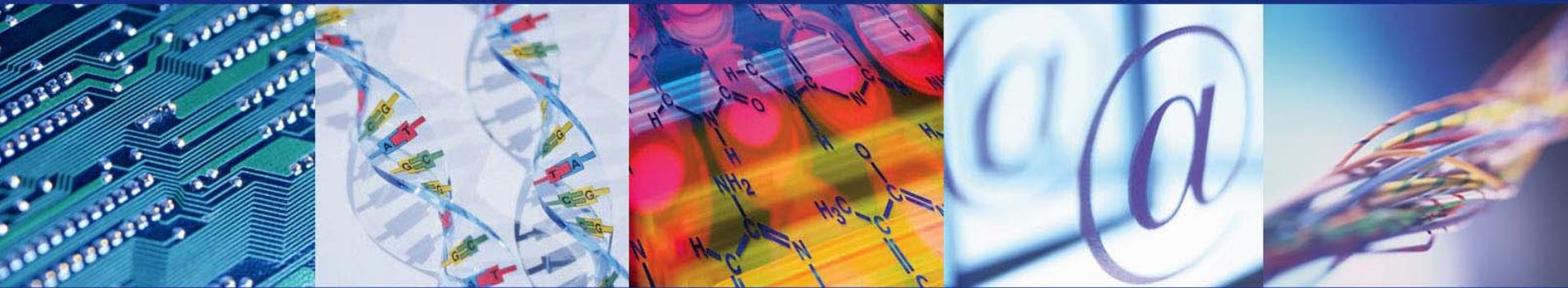
- **Without investments in innovative diagnostics**
 - Expansion of molecular diagnostics
 - Personalized medicine
 - Better health outcomes
 - Lower healthcare costs
 - Reduced adverse events

will not become a reality



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Thank you

- **Leads life science investments in the areas of molecular diagnostics, personalized medicine and wireless healthcare with particular interest in oncology, cardiology and neuroscience**
- **Serves on the board of Genomic Health (GHDX); eHealth (EHTH); CardioDx; The DNA Repair Company; Amigo Therapy; RiGen; iRhythm; Enfold and NeuroPure**
- **25 years of being an entrepreneur/founder and CEO of Life Sciences companies: Cetus (Novartis); Axion (Bristol Myers); OnCare**
- **Board Member of the California Institute for Regenerative Medicine; serves on the advisory councils of the Harvard Center for Genetics and Genomics and the Stanford Neuroscience Institute; a member of the Personalized Medicine Coalition and an honorary trustee of the National Childhood Cancer Foundation**