

BioPharma Services **Companion Diagnostics**

Expert drug and diagnostics **co-development**

Our CDx team offers expert therapeutic area, scientific, and regulatory guidance to identify and develop the ideal companion diagnostic tailored to your novel therapeutic.



Therapeutic expertise

We support precision medicine solutions across a wide range of disease areas

Our therapeutic-area experts work with you.

- Gene therapy and adeno-associated viruses (AAVs)
- Cancer and immuno-oncology
- Neurodegenerative diseases
- Rare and complex genetic diseases
- Infectious diseases
- And more

Taking your product from bench to bedside

Our team includes experts across every step of development, from biomarker assay development to clinical trial assay to companion diagnostic and ultimately commercialization.

Regulatory

Demonstrating the safety and efficacy of your device

Our experienced regulatory team can support a broad range of submissions, including:



PMA



SR/NSR



Design control



IDE

Asking the right questions **to uncover the best answers**

Together, we can develop the precise testing and therapies that can provide new hope to patients and their families.

- What test modality maximizes access?
- What FDA pathway is most favorable?
- Does the test modality/biomarker align with a commercialization strategy?
- How will the test result be used to control access? (cutoff)

Development process

Our team can help you determine key elements of your development process

- Defining the biomarker (eg, specific variants, proteins, antibodies)
- Selecting the biomarker analyte (eg, DNA, RNA, protein, IgG)
- Selecting the specimen type (eg, serum, saliva, tissue)
- Selecting the technology (eg, next generation sequencing [NGS], polymerase chain reaction [PCR], immunohistochemistry [IHC], enzyme-linked immunoassay [ELISA])
- Selecting the cutoff (eg, number)



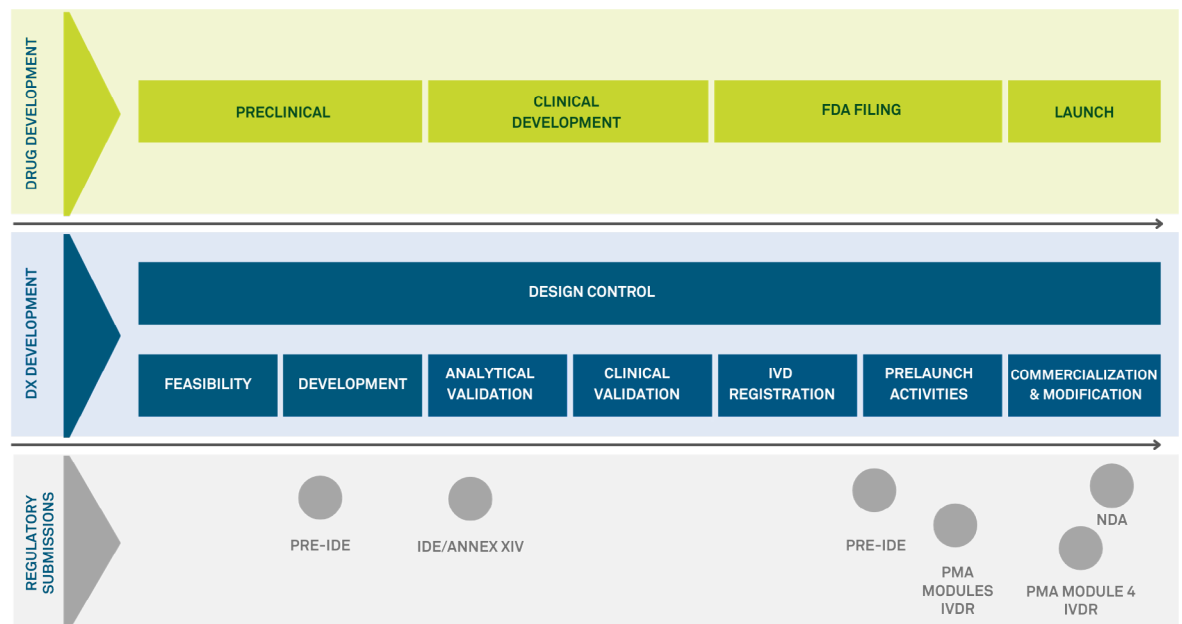
Experienced team

Our experienced team recognizes the time and effort you've invested and are committed to supporting your needs. We are dedicated to providing the highest quality lab support services to help bring your innovative new treatments to market.

- Project management
- Therapeutic area expertise
- Lab science expertise

You can count on Quest Diagnostics Pharma Services to support every step of your assay development

Your partner, from **clinical trial assays to CDx development**



Visit BioPharma.QuestDiagnostics.com to learn more about our leading companion diagnostic development services

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