PRECISION for medicine

EUA to 510(k) Conversion for COVID-19 Diagnostics

Learn More: PrecisionForMedicine.com

Our Precision for Medicine experts can support you through the process of securing FDA clearance for your COVID-19 diagnostics. Your COVID-19 test products with Emergency Use Authorizations (EUAs) will soon have to comply with US FDA 510(k) requirements. Our experts will help you do what's needed to comply with these requirements and obtain clearance to remain on the market.

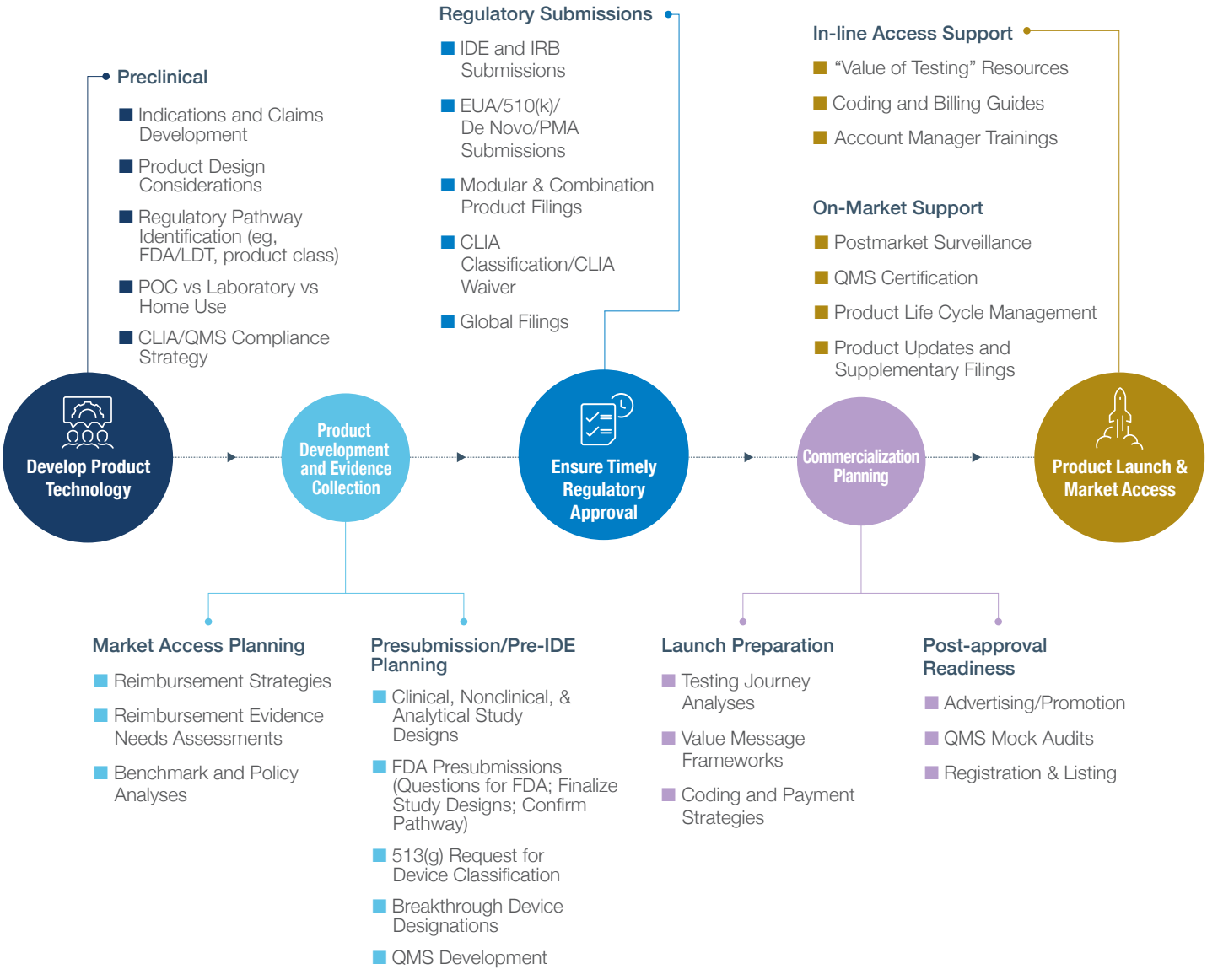
Experience With COVID-19 EUAs and 510(k) Clearances

- EUA submissions for COVID-19 diagnostics
- 510(k)/de novo/PMA submissions: global modular and combination product filings
- Preclinical planning and strategy: product design considerations
- Clinical, nonclinical, and analytical study designs to meet testing, FDA guidance, consensus standards, and clinical data requirements

COVID-19 Biospecimens

- **Clinical Specimens**
  - NS, NP, OP, Saliva, Serum, WB, DBS, PBMC
  - RNA, IgG, IgM
  - Vaccine Recipients
  - Bulk, Pools, Aliquots
- **Validation Sets**
  - Specificity (Interference)
  - Sensitivity (CT values)
- **Panels**
  - Vaccine: Pre-Post min. 5 time points, all Moderna, Pfizer, Johnson & Johnson
  - Seroconversion: Acute through convalescent (4-5 time points), natural infection, fully characterized (4-5 time points)

One diagnostics team. Integrated across functions. Streamlining test development and speeding global product launches.



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For more information about Precision COVID-19 Solutions, email us at info@PrecisionForMedicine.com or visit PrecisionForMedicine.com/510kclearance

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