A market research report on

Digital Therapeutics Regulatory Process, Updates & Trends

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Digital Therapeutics - Overview

	DIGITAL HEALTH	DIGITAL MEDICINE	DIGITAL THERAPEUTICS (DTx)
Definition	Technologies, platforms, and systems that engage users for lifestyle, wellness, and health-related reasons, collect, store, or transmit health data, and/or support life science and clinical operations are all considered to be part of the field of digital health	Evidence-based hardware and/or software products that monitor, treat, or otherwise contribute to human health are included in digital medicine	Digital therapeutics (DTx) products deliver evidence-based therapeutics interventions to prevent, manage or treat a medical disorder or disease
Clinical Evidence	Typically do not require clinical evidence	Clinical evidence is required for all digital medicine products	Clinical evidence and real world outcomes are required for all DTx products
Regulatory Oversight	These products do not meet the regulatory definition of a medical device and do not require regulatory oversight	Regulatory requirements may vary. Digital medicine products that are classified as medical device require clearance or approval	DTx products needs to be certified by regulatory bodies so as to support product claims of risk, efficacy and intended use

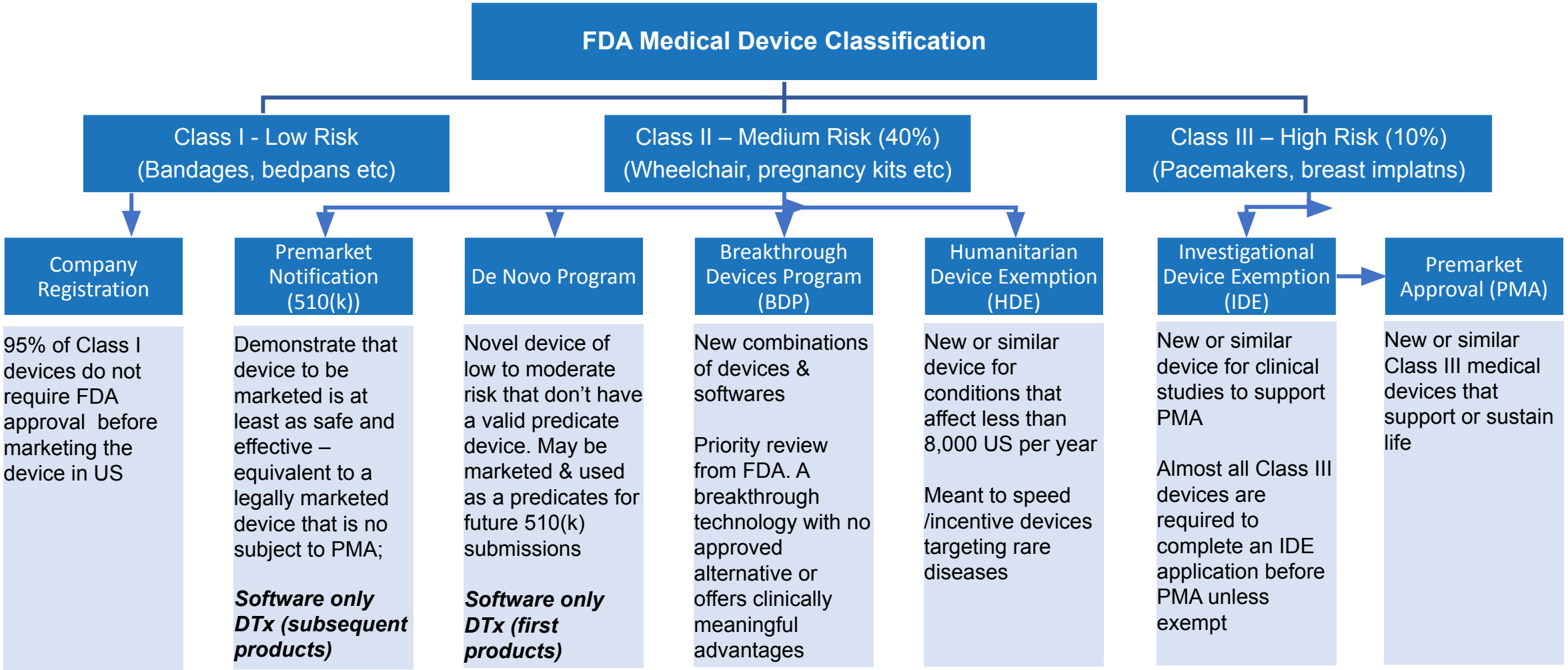
Digital Therapeutics - Definition by FDA (US)

Digital therapeutics are generally regulated as software by the FDA under the agency's software-as-a-medical-device (SaMD) category and are subject to regulatory obligations much like conventional medical devices

Summary

- Development of a Software Precertification Program (Pre-Cert) aimed to replace the need for a premarket submission for certain products and allow for reduced submission content and/or faster review of the marketing submission
- The FDA's vision for the future is that companies taking advantage of the Pre-Cert program will also be able to utilize the National Evaluation System for health Technology (NEST) system
- This aims to generate better evidence for medical device evaluation and regulatory decision making across the device lifecycle by collecting post-market, real-world data in order to affirm the regulatory status of the product and support new applications of the technology
- Section 3060 of the Cures Act excludes from the definition of "device" software functions intended for activities such as healthcare facility administrative support, healthy lifestyle maintenance, or serving as electronic patient records, so long as the function is not intended to interpret or analyze them for the purpose of condition diagnosis, cure, mitigation or treatment

US FDA Medical Device Classifications for DTx

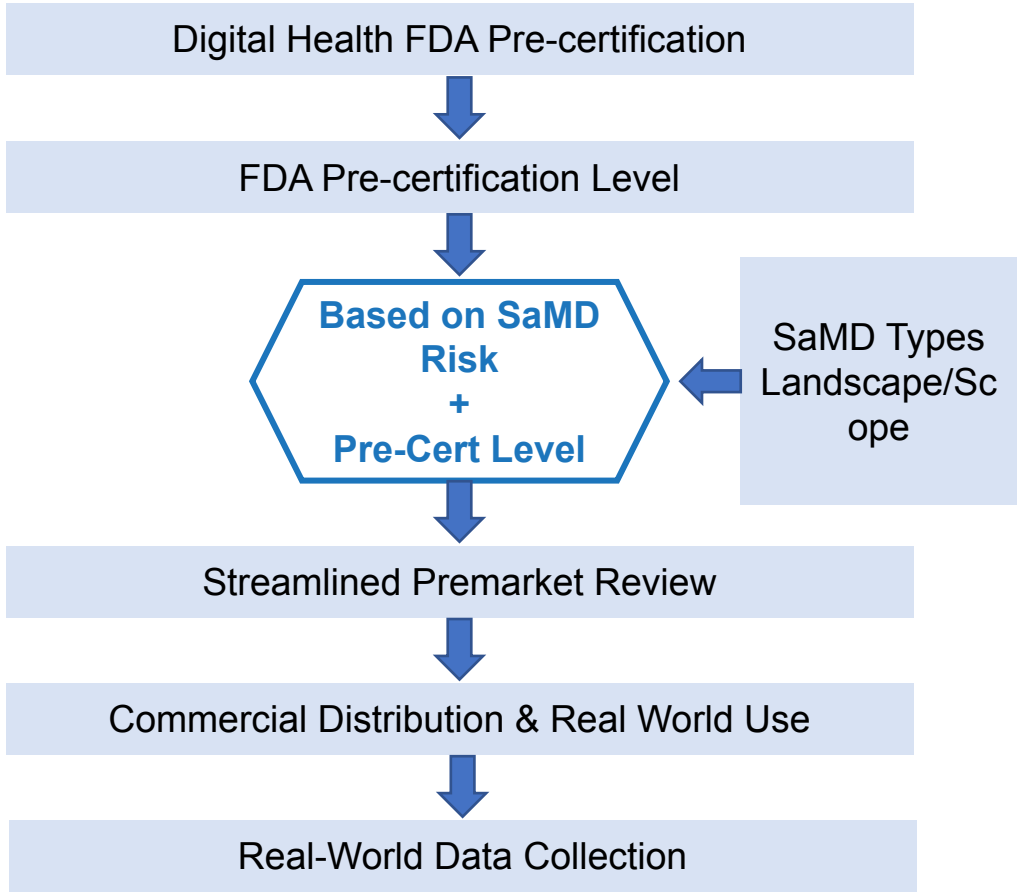


US FDA Digital Therapeutics Initiatives

Pilot Project by FDA

- FDA launched the Software Precertification (Pre-Cert) Pilot Program ("the pilot") in 2017 to foster innovative technologies and advance FDA's mission to protect and promote public health
- Pilot explored innovative approaches to regulatory oversight of medical device software developed by organizations that have demonstrated a robust culture of quality and organizational excellence and who are committed to monitoring real-world performance of their products once they reach the U.S. market
- In September 2022, the Software Precertification (Pre-Cert) Pilot Program was completed with the issuance of the Report: The Software Precertification (Pre-Cert) Pilot Program

FDA Digital Health Innovation Future Action Plan



Digital Therapeutics Regulatory Process in Germany

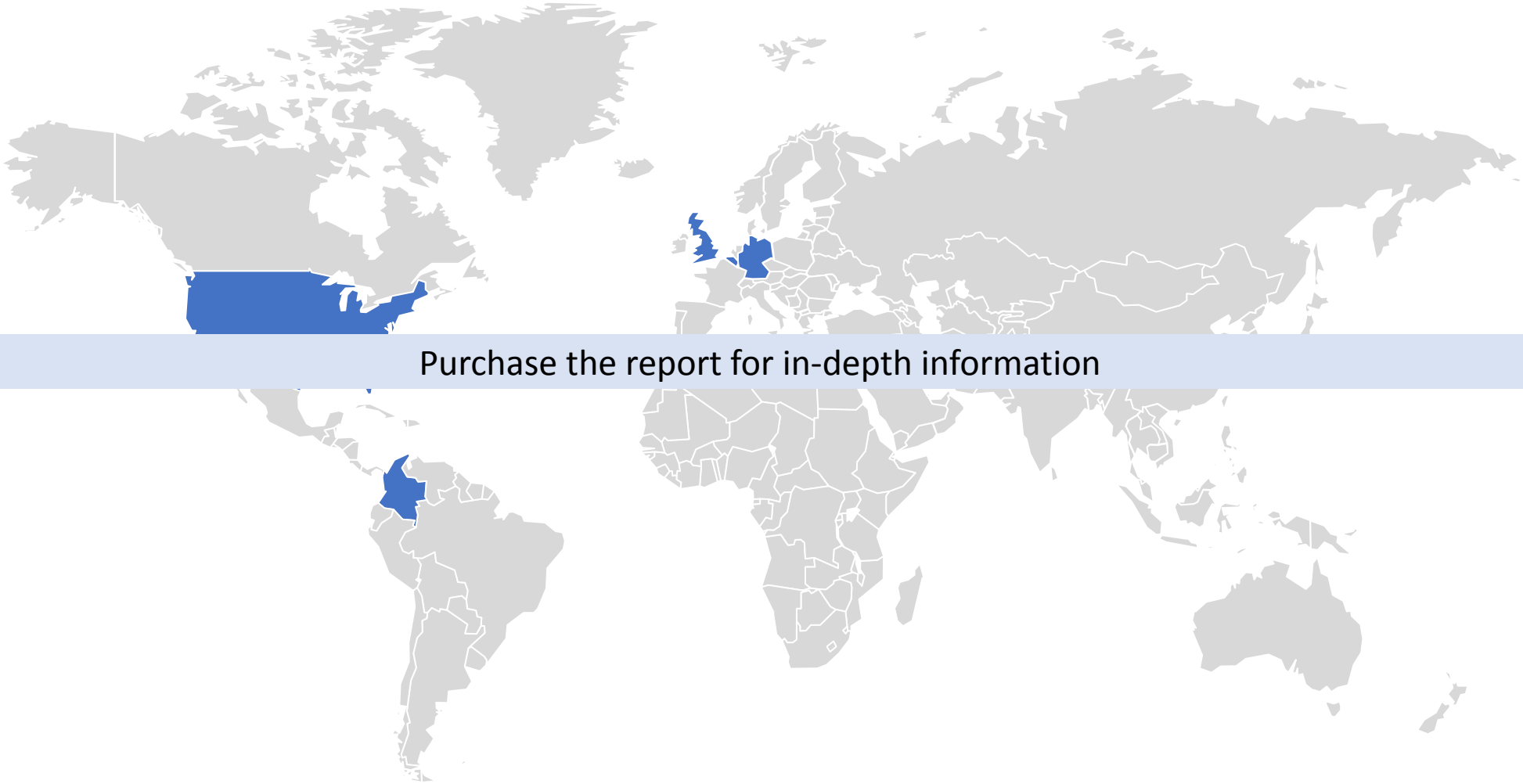
Germany

- Germany passed the Digital Care Act (‘Digitale Versorgung Gesetz’ or ‘DVG’) in 2019, it created a pathway for doctors to prescribe digital therapeutics to publicly-insured patients and receive reimbursement in much the same way as a traditional treatment
- Germany’s Federal Institute for Drugs and Medical Devices ('BfArM') has issued guidelines relating to the evaluation process digital health apps (DiGAs) must go through to be eligible for reimbursement

Regulatory Process

1. For any app to be eligible it must of the risk class I or IIa under the EU's Medical Device Directive (MDD) or, more importantly, the incoming Medical Device Regulation (MDR)
2. Most apps that self-classify as class I under MDD will be "up-classed" to class IIa under MDR, which means they'll have to adhere to stricter requirements in order to acquire a CE mark
3. BfArM's guidelines define further requirements for issues such as safety and efficacy, and the timeframe DiGA developers must meet for their DTx to be approved
4. Process has been dubbed the ‘Fast-Track’, as it allows DiGAs to be granted preliminary approval following an evaluation, after which developers have 12 months to generate sufficient evidence for full approval

Digital Therapeutics Regulatory Process – Other Countries



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Who should buy this report?

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Digital Health Entities

HealthTech Companies

MedTech Players

Other Lifesciences Companies

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Cost of this report:

$2,500

Annual Subscription:

~~*$125,000*~~ *$60,000*

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Topics of Upcoming Reports

- Will the Expiry of Humira Market Exclusivity and Entry of its Biosimilars Move the Needle in BioPharma Market?
- From the Fringes to the Forefront: mRNA is here to Transform Global Health
- Melting the Iron Triangle: 10 Healthcare Players aiming Beyond Health Equality to Conquer Health Equity
- Robotics: Embarking a New Era in Surgical Innovations
- Metaverse: Paving the way for Health 4.0
- Healthcare Future Outlook 2023
- Patient Engagement- a New Standpoint on Care that is Patient-Centered
- E-Rx, the Digital Version of Prescription Improvising the Chances of Better Patient Outcomes
- Integration of Healthcare Systems with Big Data and Data Silos

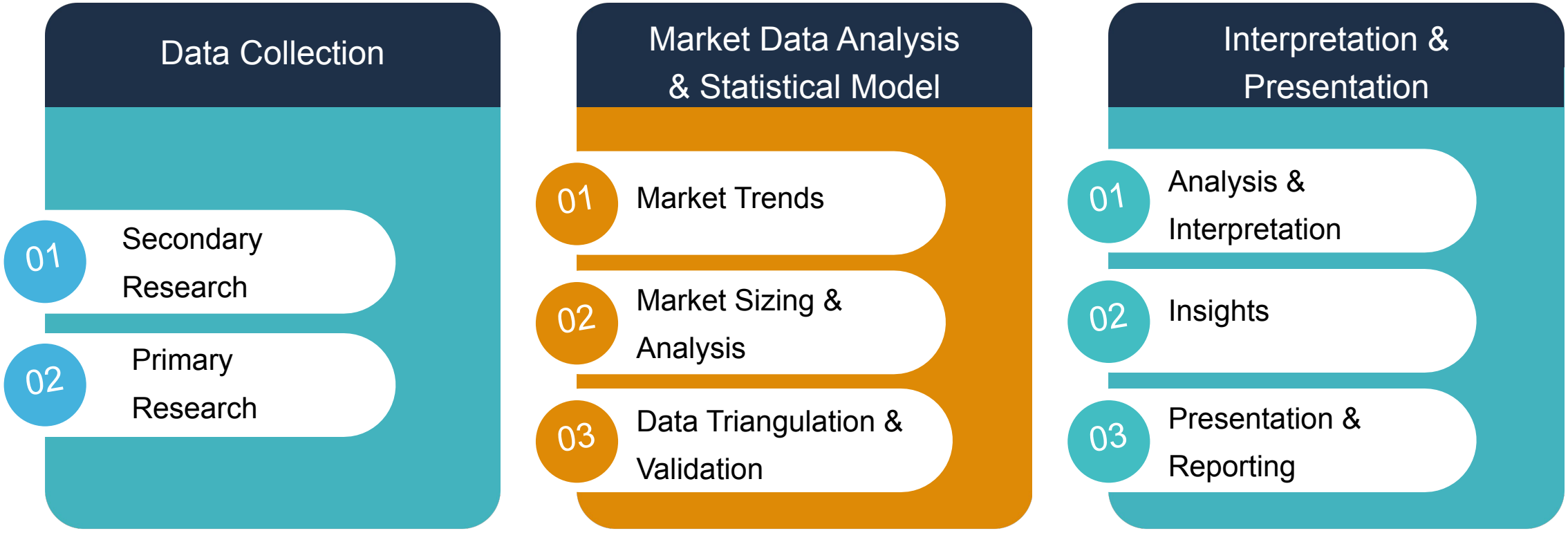
Methodology & Scope

Research Methodology

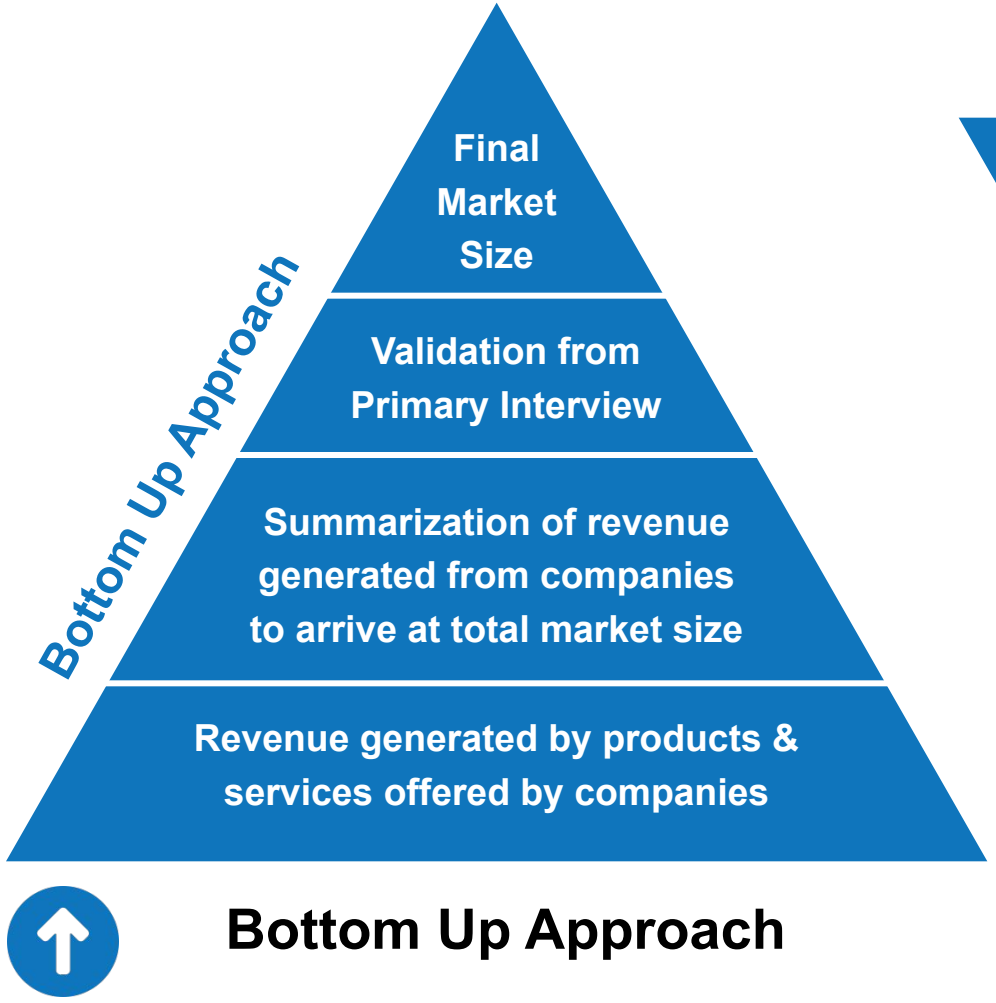
- Insights 10's research methodology delves deeper into the market, covering the macro and micro aspects of the industry. We identify the key growth drivers, opportunities, and restraints that might promote or hinder the future industry growth along with an expansive overview of the competitive landscape to help our clients make informed strategic decisions
- We implement a mix of primary and secondary research for our market estimate and forecast. The secondary research forms the initial phase of our study where we conduct extensive data mining, referring to verified data sources such as independent studies, government and regulatory published material, technical journals, trade magazines, and paid data sources
- For forecasting, the following parameters are considered:
  - ❑ Market drivers and restraints along with their current and expected impacts
  - ❑ Technological scenario and expected developments
  - ❑ End use industry trends and dynamics
  - ❑ Trends in the consumer behavior
  - ❑ Regulatory scenario and expected developments
  - ❑ Current capacity and expected capacity additions up to 2030
- We assign weights to these parameters and quantify their market impacts using the weighted average analysis to derive the expected market growth rate
- We appoint data triangulation strategies to explore different areas of the market. Our qualitative and quantitative assessments are time-sensitive, reflecting the most recent value and volume of the market across regions
- All our estimates and forecasts are verified through exhaustive primary research with the Key Industry Participants (KIPs)
- Currency used in the report is the US dollar (USD), with the market size indicated in USD million/billion (Mn/Bn)

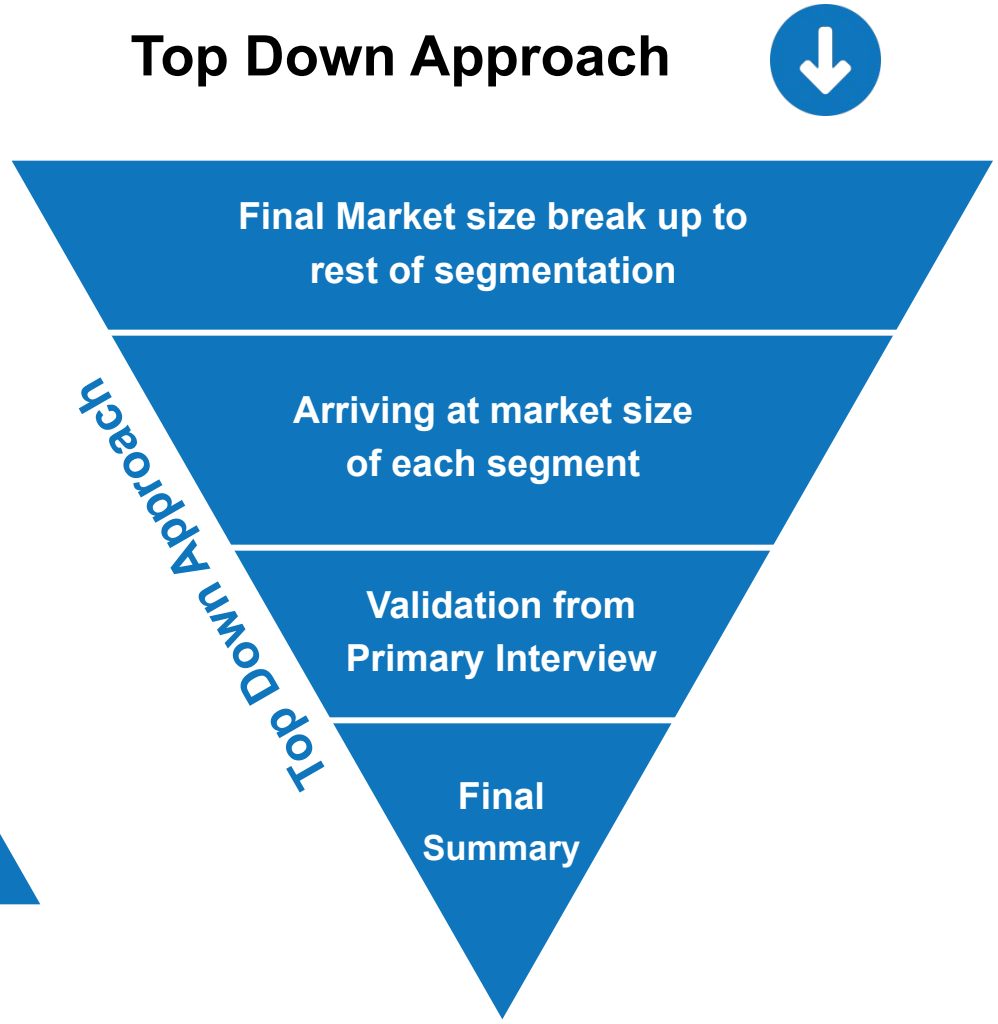
Analysis Methodology

Our Analysis Methodology involves three critical stages:



Data Triangulation & Data Validation





Key Benefits for Stakeholders from this Report

- Study provides an in-depth analysis of the market with current trends and future estimations to elucidate the imminent investment pockets
- Our tools provides stakeholders with a cohesive understanding of the industry outlook, considering the qualitative and quantitative industry variables
- Comprehensive analysis of factors that drive and restrict the market growth is provided
- Comprehensive quantitative analysis of the industry from 2021 to 2030F is provided to enable the stakeholders to capitalize on the prevailing market opportunities
- Extensive analysis of the key segments of the industry helps understand the applications and technologies used globally
- Our rigorous data collection, thorough statistical analysis and specialist assessments ensure that our clientele has a greater understanding of the industry space, supply chain, price fluctuations, competitive landscape, and other vital factors

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Time Frame	Report Attribute	Details
2021 Base Year for Estimation 2022-2030 Forecast Period	Quantitative Units	Revenue in USD Million/Billion (Mn/Bn)
	Report Coverage	Market Overview, Revenue Forecast, Market Segmentation, Growth Factors and Trends, Company Profiles, Competitive Landscape, Regulatory Landscape, Future Opportunities
	Customized Report	Report Customization (5 working days) with purchase. We will provide you with data that is currently not a part of our scope as a part of customization
	Pricing and purchase options	Avail customized purchase options to meet your exact research needs

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What kind of Data is Presented in this Report?

This report presents data, which is:

Reliable

The report is prepared using a proven methodology and insightful research

Expert-verified

The data is prepared by a team of highly qualified & experienced research analysts & vetted by our local associates

Real

Allowing you to confidently make smarter business and strategic decisions

Comprehensive

Covers everything you would need to know about the market including market size, competitive analysis & much more

Easy to read

You do not have to be a market expert to understand what really is happening on the market and how it works


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