A Comprehensive Analysis of the FDA 510(k) Process

Industry Practice and Implications for Reform

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Webcast Briefing—December 22, 2010

Background: Previous Study on Medical Device Development Models

Previous Study

Pietzsch JB, Shluzas LA, Paté-Cornell ME, Yock PG, Linehan JH. "Stage-Gate Process for the Development of Medical Devices." *Journal of Medical Devices*, 3:2 (2009).

CD of full study report available from InHealth (www.inhealth.org)

STANFORD biodesign

Study on

Medical Device Development Models

Final Report

Prepared for

INHEALTH Institute for Health Technology Studies

InHealth – The Institute for Health Technology Studies

by

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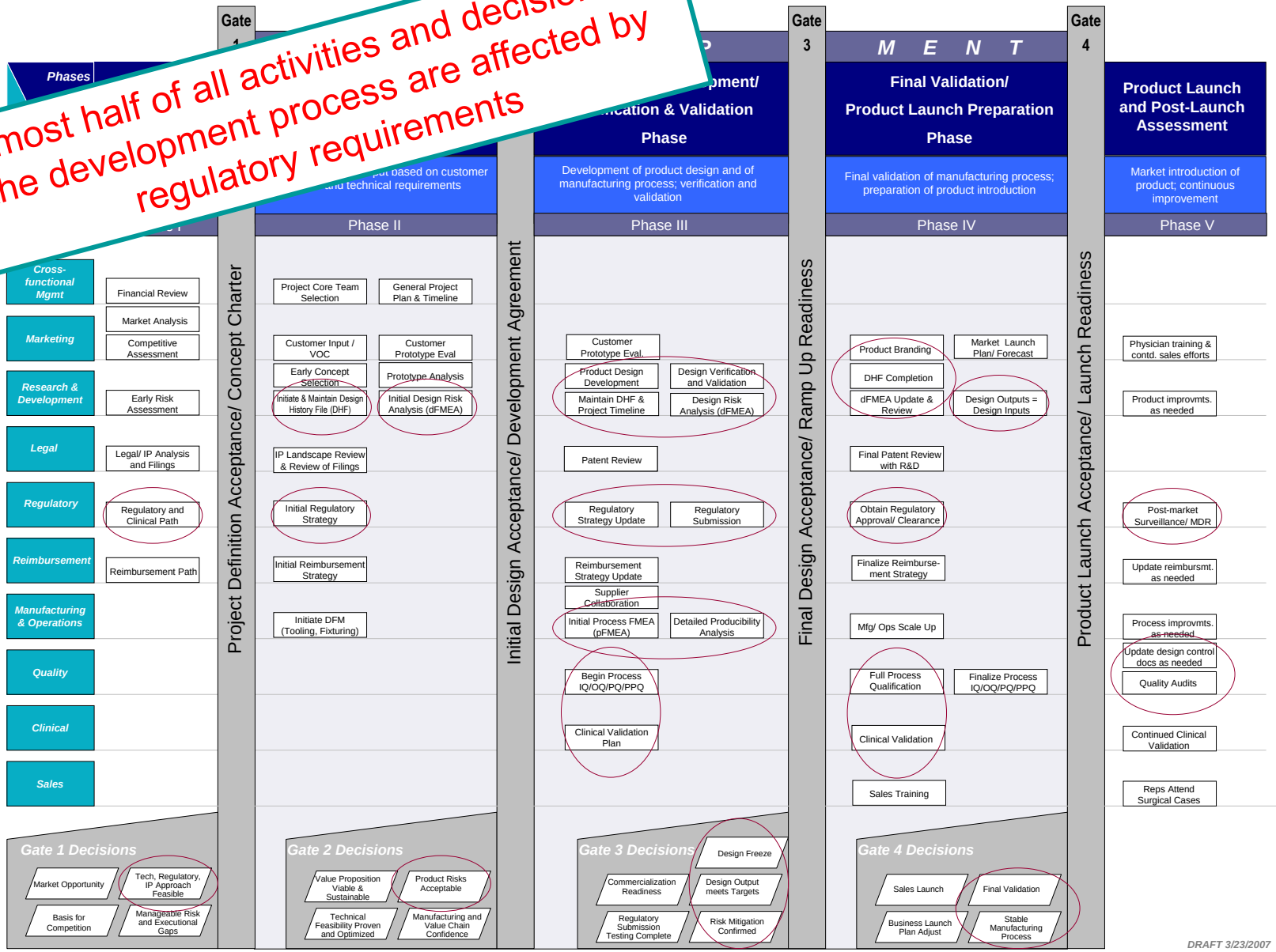
September 30, 2007

Regulatory Requirements Heavily Influence Device Development

Almost half of all activities and decisions in the development process are affected by regulatory requirements

Medical Device Development: High… …n of Development Phases and of Functional Activities



Observations on 510(k) Reform Debate

Observations

- Current discussions on 510(k) often rely on anecdotal experience
- Lack of systematic evidence
- Lack of data about process efficiency
- Misconceptions and misunderstandings about nature and implementation of current process
- Discussion could build more heavily on expertise of regulatory professionals

Study Objectives

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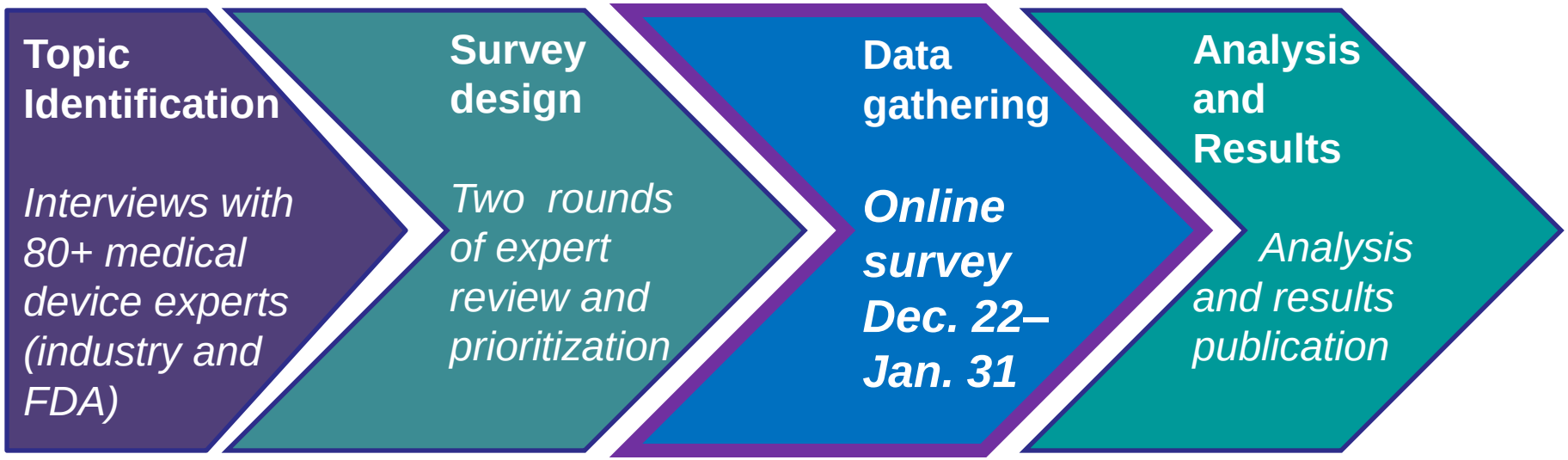
Contribute to current reform debate by conducting a large-scale online survey that focuses on:

- Timelines
- Interactions with the agency
- Challenges in current implementation and specific opportunities for improvement of the process
- Data collection to elucidate aspects of the process that are often misunderstood or where misperception exists
- Comparative experience with international regulatory programs

Survey Methodology and Timeline



8/2010 12/22/10 4/2011

Survey Design

Survey Elements

- Demographic info (9 questions)
- Predictability (13 questions)
- Interaction with FDA (15 questions)
- Process (15 questions)
- Device-specific experience (34 questions)

Requirements for Participation

Participation

- Respondents need to have been involved with a 510(k) submission over the course of the past 3 years
- Participation anonymous
- Time requirement: 45–60 minutes (can pause and resume)
- Need to complete survey by January 31, 2011

Information on Survey Access

Access to survey and resource center: **www.510k.net**