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**RASOR RESOURCE NEWSLETTER**  
*Valuable, Proven Tools for Medical Device Industry Executives*  
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Greetings Julia:

We thank our readers for the great response to our last newsletter where we shared the value and use of the Rule of Three in clinical trial sample size determination. Also, in the email announcing my talk "Entrepreneurship in Silicon Valley" at the annual Santa Clara University Women in Business Conference, we provided recent investment statistics for Silicon Valley. In this issue, I am very pleased to present a high level diagram of the five phases and decision gates of developing a medical device along with activities of the major functional groups. I am sure you will find this diagram, courtesy of the Stanford Biodesign program, as valuable a tool as I have in walking my clients through timelines and tasks and identifying milestones and needed resources. Enjoy!!

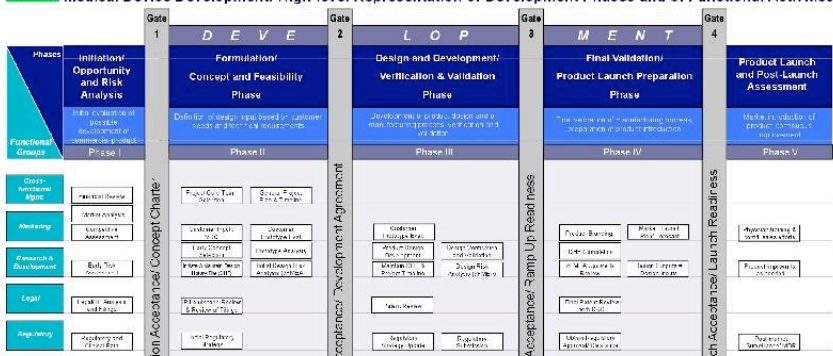
**Julia S. Rasor**  
 Medical Device Strategist and Entrepreneur

**Resource**

**Topic:** Medical Device Development Phases and Functional Activities

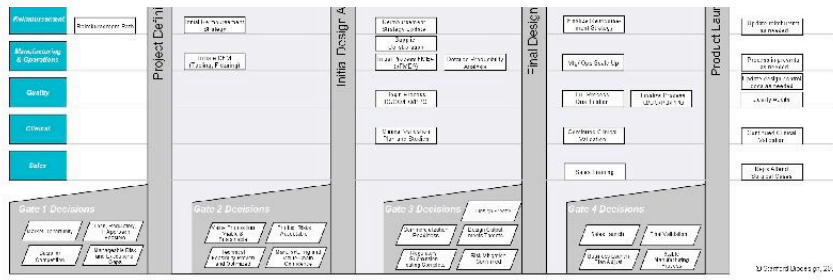
**Problem:** In general, there is lack of a concise means to visualize the stepwise process of medical device development that includes the chronological phases, decisions that need to be made to move to the next phase, and the activities of the major functional groups in each phase.

Medical Device Development: High-level Representation of Development Phases and of Functional Activities



**Solution:** The diagram pictured on the left ([click here to enlarge](#)), which was the result of a one-year research study on Medical Device Development Models performed by a research team at Stanford University's Program in Biodesign [1], provides a high-level representation of medical device development.

The diagram identifies five major



phases, separated by four decision gates. Pre-development activities occur prior to Gate 1, development activities occur between Gates 1 and 3, and product launch and post-market assessment occur in the phase following Gate 4. In the diagram, the major functional groups are identified in turquoise

boxes on the left. Major decisions are shown (in parallelograms) at the bottom of each phase. Upper level activities for each functional area are provided in boxes within each phase. The horizontal progression represents a generalized time-line. The major milestones / gates can occur at different times in the development process depending on the type of device. The five major phases and decision gates include the following [1]:

- Phase 1 / Gate 1 - Initiation, Opportunity, and Risk Analysis*
- Phase 2 / Gate 2 - Formulation, Concept, and Feasibility*
- Phase 3 / Gate 3 - Design and Development, Verification, and Validation*
- Phase 4 / Gate 4 - Final Validation and Product Launch Preparation*
- Phase 5 - Product Launch and Post-launch Assessment*

The diagram shows a process that is most applicable to PMA and 510(k) devices that require some form of clinical data. It should be noted that although each development phase is presented in a discrete manner, the iterative process of device development does not always follow the linear, idealized model, but rather exhibits "fuzzy" boundaries between decision gates. Because of iterations in the process, it may occur that some parts of a development project are already in a more advanced phase, while certain activities of a previous phase need to be repeated at the same time [1].

In summary, the study produced the following key recommendations for industry [1]:

- Managing the development process successfully requires a thorough understanding of the regulatory requirements. It seems clear that developing and executing a strategy which takes these requirements into account is needed. In particular, the determination of an appropriate regulatory pathway and the implementation of procedural steps and processes, that satisfy FDA's Quality Systems Requirements, are critical.*
- In developing and executing their strategy, manufacturers should identify early on the outcomes (i.e., endpoints) that will most likely be used by regulators and payers to evaluate the device and understand what underpins these outcomes. This requires the development of a clear and systematic understanding of the relationships between the engineering, clinical, and economic aspects of the technology, and the impact of early-stage decisions (e.g., engineering design choices, target population, etc.) on the identified outcomes of interest.*
- Early and well-informed communications with the FDA should be initiated (e.g, through Pre-IDE meetings) to discuss the nature of the technology, and to determine jointly the most appropriate means to demonstrate the safety and effectiveness of the technology. This is particularly important for devices for which no precedence or guidance document exists. Sharing with the FDA the specific features of the technology and its background and making well-founded recommendations for testing can serve a manufacturer well, and can lay the foundation for a significant reduction in uncertainty about the regulatory process.*

The results of the Stanford device development model study were recently presented at an [Industry/FDA meeting \(click here\)](#) organized by the study sponsor, the Institute for Health Technology Studies (InHealth). The full study results are available through InHealth (call 202-783-0940 or email

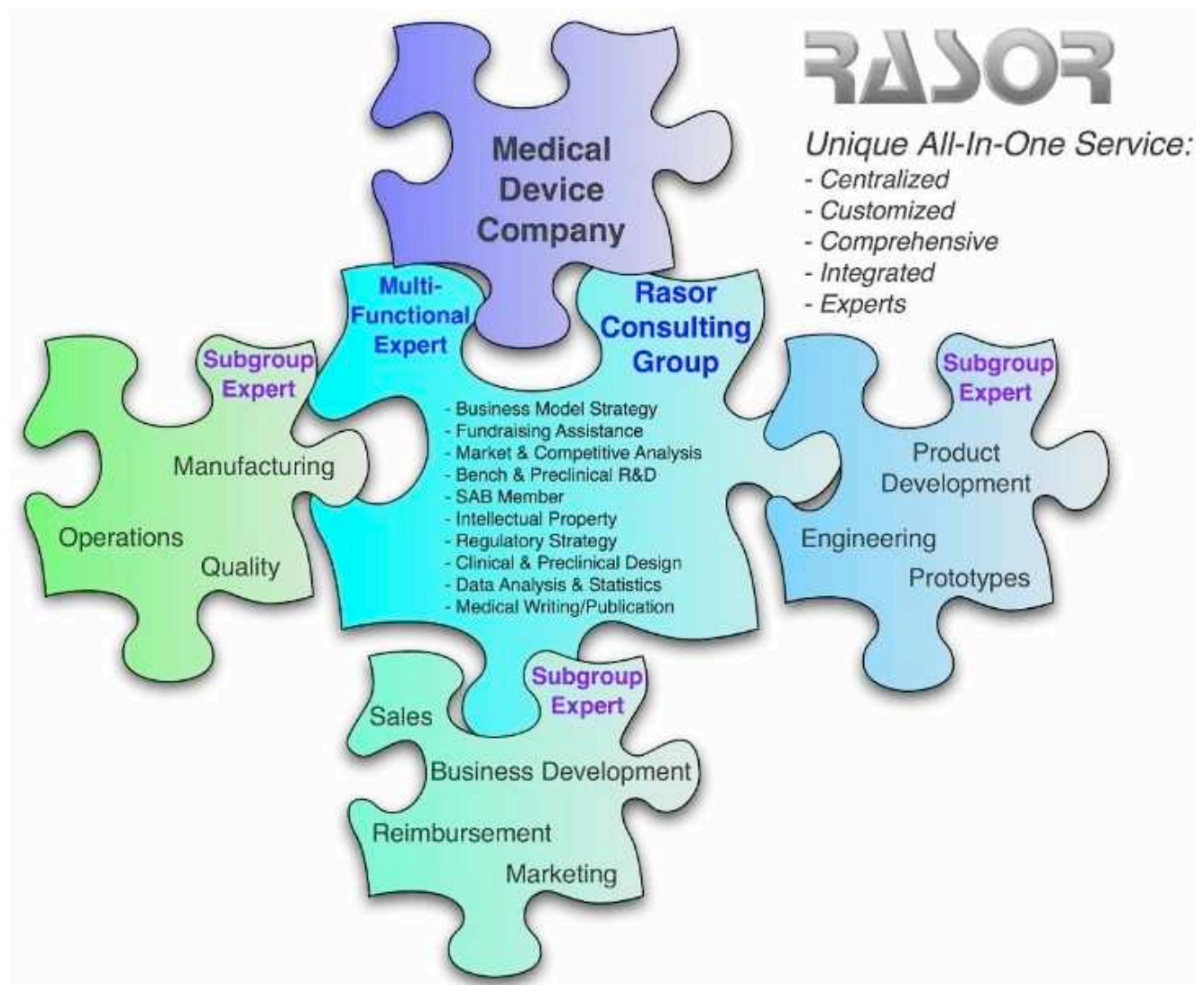
InHealth@InHealth.org for a free copy).

## Reference

1. John H. Linehan, Ph.D. (Principal Investigator), M. Elisabeth Paté-Cornell, Ph.D. (Co-Principal Investigator), Paul G. Yock, M.D. (Co-Principal Investigator), Jan B. Pietzsch, Ph.D. (Investigator), Lauren A. Shluzas, M.S. (Research Assistant). Final Report on Stanford Biodesign Medical Device Development Models Study. Prepared for InHealth - The Institute for Health Technology Studies. Page 65. September 30, 2007. Copyright Stanford Biodesign, 2007.

**Acknowledgement:** Many thanks to Study Investigator Dr. Pietzsch who granted us permission to include the diagram in this issue of Rasor Resource: Jan B. Pietzsch, Ph.D., Consulting Assistant Professor in Stanford University's Department of Management Science and Engineering and President and CEO of Wing Tech Inc.

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Julia S. Rasor, MSc, is a multifunctional strategic entrepreneur with a track record of leading very successful solutions for business, clinical, and regulatory roadblocks. She is the inventor of a \$100M-a-year revenue medical product, holder of 6 patents with 7 pending, former CEO founder, member of five scientific advisory boards, founder of the 25-year Rasor Consulting Group at [www.MedicalDevice.com](http://www.MedicalDevice.com), and author of 50 publications.

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