Medical Affairs Continuum

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From Initiation

To Commercialization

And Beyond

Advantages of involving Medical Affairs Early in the Process of Device Development

Experienced Chief Medical Officer (CMO)

- Serves as part of leadership team/brain trust
- Insures non-clinical animal studies address the endpoints of future clinical studies
- Helps provide industry experience from a clinical and medical perspective

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Additional Early Medical Affairs Activities

- Assists with the 510 K or PMA strategy
- Reviews design from perspective of an end product medical user
- Involved with FDA and other regulatory interactions
- Support with Human Factor considerations
- Supports the rationale for reimbursement

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Medical Affairs From the Beginning

Essential questions to ask:

- What is the scientific and commercial medical assessment of the technology?
- Is this a viable product?
- Is there a medical need?
- Is this a practical design?
- Can it pass regulatory scrutiny?

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Essential Questions

- Will it be prescribed?
- Is there intellectual property protection?
  - In what countries?
  - Is there freedom to operate?
- Can it be reimbursed?

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If Clinical Trials Are Required

Clinical Trial Plan

- Helps create clinical protocol and investigator brochure
  - Include Pharmacoeconomics when possible
- Contract Research Organization (CRO) selection
- Clinical trial oversight
- Medical Monitoring of clinical trial
- Safety and Pharmacovigilance
- Review of statistical and clinical report

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Ideal Requirements for Start Up Chief Medical Officers

- Entrepreneurial physicians with business experience
- MDs who have been responsible for P&L or have good understanding of its importance
- Able to interact with academic and community key opinion leaders (KOL)
- Successful interaction with the FDA and other regulatory bodies

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Ideal CMO
(Continued)

- Provide medical and scientific leadership
- Experienced working with marketing, sales, and business development
- Able to analyze and interact with technology transfer departments
- Able to create and execute cost effective clinical trials
- Experienced in contract research organization selection and management

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Post Marketing Medical Affairs

- KOL Development
- Publication Planning and Execution
- Pharmacoeconomics and Reimbursement
- Medical Information
- Safety and Pharmacovigilance Oversight
- Assistance with Potential Partnerships
- Scientific and Commercial Medical Assessment of Technology Transfer

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Artificial Intelligence (AI)

New Initiatives

- Incorporation into diagnostics
  - AI predicted a patient's response to immunotherapies by analyzing CT scan images for a personalized "radiomic signature," without the need for a biopsy. (Sun R. 2018)
    - Experienced radiologists were not able to predict this response

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AI
(Continued)

- Striving to streamline safer and more effective therapeutics

Require medical synergies

- In coordination with experienced therapists
- Oversight of algorithms

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AI in Therapeutics

Holistic approaches

- General patient improvement
  - Assist in improving lifestyle choices
  - Improving medication adherence
  - Gathering individual data with impactful behavior changing directions
  - Practical outcomes mined in big data

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AI in Therapeutics
(Continued)

Specific care as with Psychological AI Digitals Rx

- Future prescription therapeutic AI
- Interactive psychological therapeutic treatments

Self management programs as with diabetic programs

- Virtual lifestyle management program

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Benefits of AI in Product Development

- Ability to generate and test novel hypotheses by analyzing immensely complex sets of data
- This type of AI shows particular promise within the pharmaceutical industry for potential new product candidates
- The ability to generate and test novel hypotheses much more efficiently than the traditional process allows, enabling faster and more accurate clinical trial periods

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Blockchain

- Blockchain can be defined as a distributed ledger technology that can record transactions between parties in a secure and permanent way
- Blockchain is a tamper-proof digital ledger that records activity in a transparent, secure, and accessible format
- Tool for improving security, transparency, and efficiency, its potential applications in the technology and medical device industries are numerous

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Examples of Blockchain

- Enforcing Human Subject Regulations using Blockchain and Smart Contracts
- Leveraging Blockchain Technology to Enhance Supply Chain Management
- Blockchain as a Foundation for Sharing Healthcare Data
- Use of the blockchain offers the opportunity for an immutable ledger, which shows not only where the device is but where it has been in its lifecycle, as well as which manufacturer, reseller, and the serial number area associated with the device, aiding regulatory compliance. (Krawiec R 2016)

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Medical Affairs Unique Continuum in Medical Technology

- Provide essential insights for practical cost effective device development and commercialization
- Assist with key early organizational essentials
- Scientific rationale and medical need for product development
- Help incorporate AI, Blockchain, and future advances into corporate planning and growth

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