



Building Collaborative Networks for Innovation

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Innovation

Innovation is a new way of doing something or "new stuff that is made useful". It may refer to incremental and emergent or radical and revolutionary changes in thinking, products, processes, or organizations

Medical Devices

- “Being Useful” \leftrightarrow Reimbursement
 - Same outcomes with lower cost
 - Better outcomes for same cost
- The “so what” rule
- FDA now starting to look at clinical utility i.e. not just safety and efficacy

From bench to bedside ?

- Not generally the case with medical devices
- From bedside -> bench -> bedside
- Clinicians are best qualified to judge clinical utility and clinical need
- Innovation needs high level of clinician involvement
- Less of an issue with diagnostics and pharma

“Made Useful”

- Manufacturing technologies a key element
 - Proximity to R&D
 - Relevance to industry e.g. Quality standards
- Process innovation
 - In many instances more critical than the product innovation

Cluster - Testing

- Testing and simulation
 - Anatomical models
 - Regulatory testing
 - Pre-clinical testing
 - Clinical testing

Staffing

- MNC base
 - R&D
 - Quality Systems
 - Manufacturing Skillsets
 - Regulatory Affairs
- Marketing gap

Collaborations

- Medical Devices
 - Clinicians -> Company
 - Company (Product) -> Company (Process)
 - Clinician<-> Researcher-> Company
- Diagnostics and Pharma
 - Researcher -> Company

Barriers

- Difficulties in financing translational research within industry – need for an SBIR system
- Very little device clinical trial work in Ireland
 - New CRFs
 - Protected time
 - Parallel Ethics and IMB approval
- IP not well developed enough
- Realism on royalty rates

Conclusions

- Powerful cluster effect exists for medical devices, largely driven by MNC and sub-supply base for medical devices
- Further innovation and collaboration in the medical device sector will grow with greater clinician involvement
- Early research gains likely in the areas of
 - Diagnostics and Pharma
 - Regenerative Medicine



Thank You

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