

The Impact of the Convergence of Biologics with Devices: *Scientific, Developmental, and Business Strategies for Convergence*



cardio dx

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Two “Convergence” Cases

- **Guidant Corporation**

- Fortune 500 medical device company
- Acquired in 2006 by BSX, ABT
- Had to transform from electromechanical device company to a biopharma delivery company



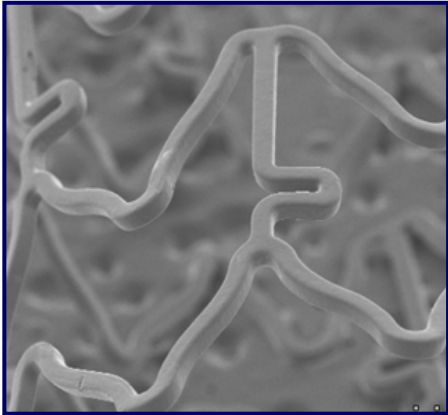
- **CardioDx, Inc.**

- Pre-commercial, privately held company
- Personalized medicine in cardiovascular disease
- Aims to better stratify medtech therapy delivery through molecular diagnostics

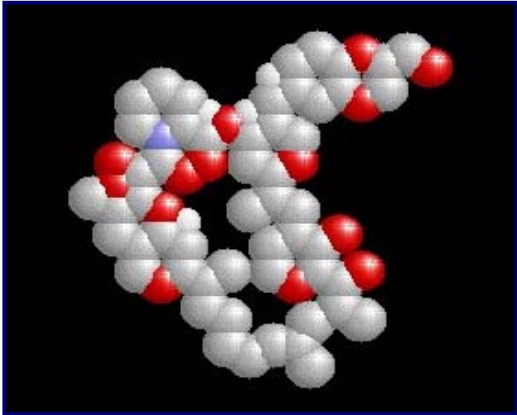


Case 1: Guidant & DES

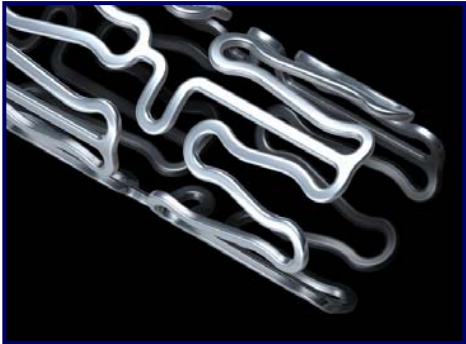
Control Release Coating



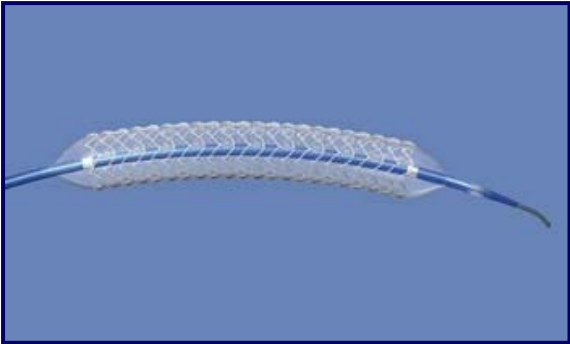
Biopharmaceutical Agent



Stent Platform



Delivery System



Convergence Proved Difficult

- **Technology Challenges**

- Controlled-release biopharma delivery in a dynamic environment is very, very hard
- Biomaterials and pharmacokinetics critical

- **Operational Challenges**

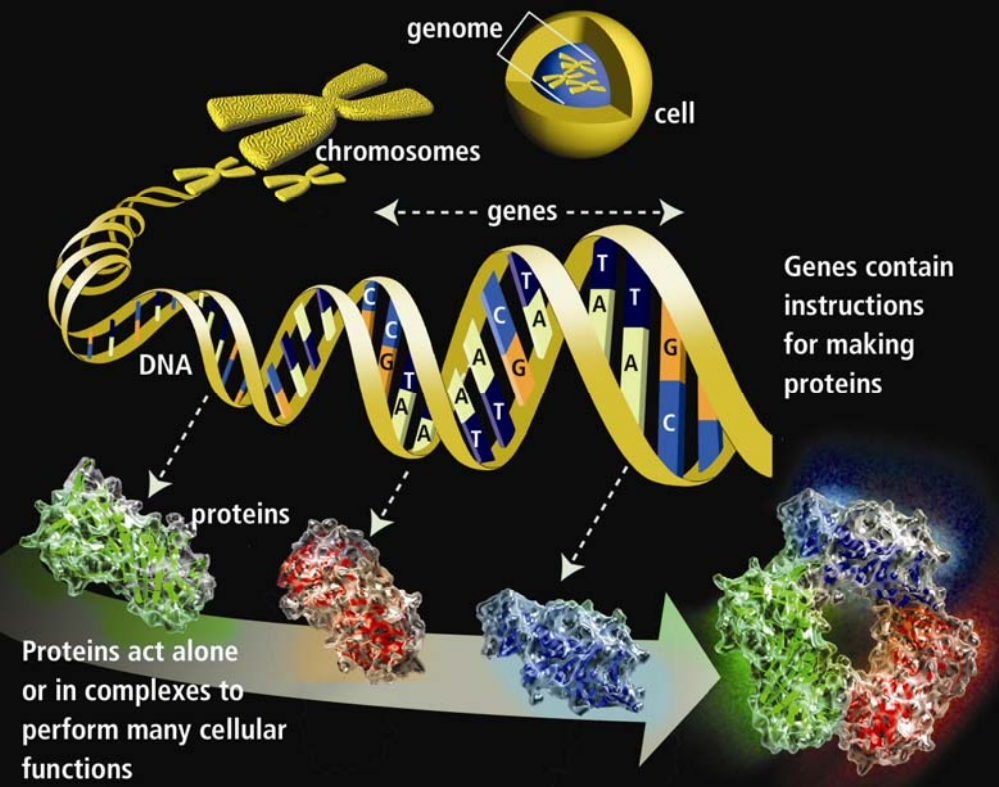
- Chemistry, manufacturing controls
- Biopharmaceutical regulatory requirements
- Clinical trials more complicated, more expensive
- Building new competencies in R&D organization

- **Development timelines went from 18 mo to 4-5 yrs!**

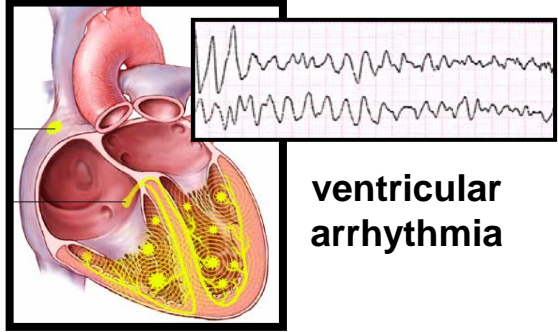
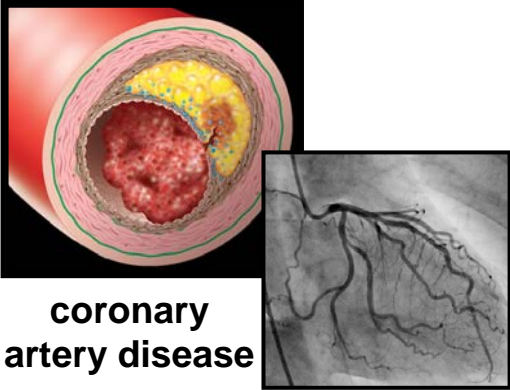


Case 2: CardioDx & Personalized Med

Converge molecular information with clinical decision making in cardiovascular medtech delivery



U.S. Dept. of Energy



Convergence Hurdles

- **Technology Challenges**

- Extremely high levels of process control in lab automation required
- Analysis platform technologies in flux
- Gene and SNP correlation to multigene diseases still being discovered

- **Operational Challenges**

- Bioinformatic and IT platform operations
- Major regulatory controls with molecular data
- Proving value of personalized medicine to physicians and payers
- New models for operating costs, margins, pricing

