Medical Device Opportunities in India Today : Marketing, Engineering and More

http://www.amritt.com/med-device

A recorded version will be available at http://www.amritt.com/Med-Device-Webinar

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Chicago Metra Buys 400 Automated External Defibrillators

- $1 million order on Cardiac Sciences Corp.
- For ~400 PowerHeart G-3 automated external defibrillators
- Cardiac Sciences is owned by Bangalore India-based Opto Circuits, $64 million M&A

Medtronic India expands audiology market

August 2013 – Pilot program, ***Shruti***;
70,000 patient pilot includes

- Medtronic India
- A Mobile health startup with MIT roots
- An Indian design firm
- Dr. Shroff's Charity Eye Hospital, New Delhi, and Health Management & Research Institute, Hyderabad.
- **Goal:**
  - **Improve diagnosis and treatment of ear infections**

Companies to leverage Emerging Economies

- Working with corporate and business unit leaders at large and emerging device companies in America and Europe
  - Helping them to engage with India/China etc.
- Engage directly with markets or via partners.
- Access technologies, products, tech skills.
  - Directly or via partnerships.

Amritt Clients include large and small medical technology companies globally

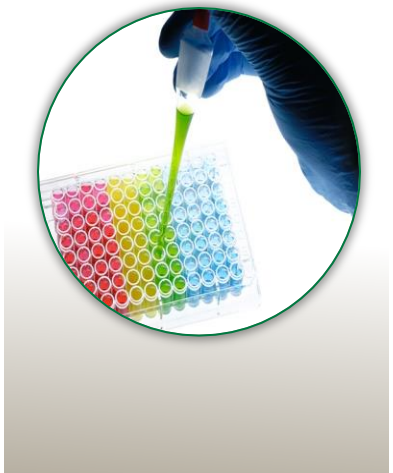
Harvard Business Review | MEDICAL PLASTICS DATA SERVICE | medtechinsider | Bloomberg Businessweek

M&M WEST | IAOP International Association of Outsourcing Professionals | MD&DI Medical Device & Diagnostic Industry | MedTechWorld MEDevice San Diego Conference & Showcase | 1983 - 2013 M&M 30th Anniversary EAST

Agenda

1. Sell *Made in USA* product in India

2. Use India's Engineering Skills for Western markets



Globalize: Reach Next 3 Billion Medical Consumers

Some Key Characteristics of India Market

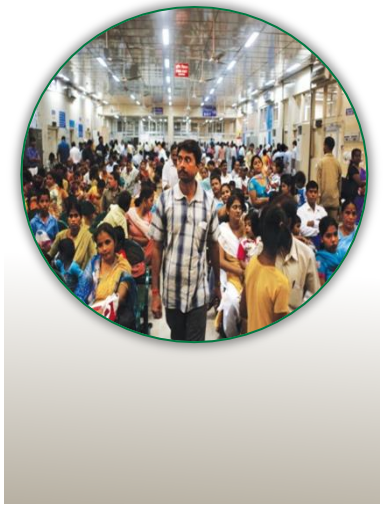
- Small wallets (patients, doctors, hospitals)
  - Big chunk of market is out-of-pocket
- Very Low-cost labor (at hospitals, clinics)
- Lower legal risk
- "Radical Redesign" can produce 3x sales multiple compared to "Incremental Cost and price Reduction"

India is Not China 2.0

- Demand side economy *vs*. China's supply side situation
  - Creating airlines before airports; cars before highways
- To maximize long term India profit:
  - Reach down to grab the market, before unmet needs are filled by Indian cos.
- Waiting for India to rise up to developed country expectations of price/quality may allow nimble Indian upstarts to eat your lunch.

India: a Big, Relatively Untapped Market

- 1.2 billion people, $1.8 trillion economy, growing at ~6%
  - Healthcare market growing at 12-15% annually
  - ~50% of population has no access to western-style healthcare
- Medical Device market is ~$4 billion in 2013*
  - Foreign companies have 65% market share by value



*Amritt estimates

- 70% of healthcare expenses are out-of-pocket
- Private Insurance is small, but growing (1% in 2009, ~8% in 2014)
  - Govt. as payer: community insurance for people below poverty line
- Govt. is doubling healthcare spend to 2.5 percent of GDP
  - Most of healthcare is a state (not federal) subject,
  - Low Bidder Wins
- Infectious Diseases still rampant
  - Malaria, Cholera, T.B.
- Lifestyle Diseases are rising rapidly
  - Diabetes, Cardiovascular

Recent International Med-tech Entrants

California's Cepheid, Inc.: $416 million global sales

- GeneXpert MTB/RIF molecular diagnostic blood test for tuberculosis
  - Cartridge Based Nucleic Acid Amplification Testing
  - Much faster than sputum Culture; also tests for MDRT
  - Special price negotiated by Gates Foundation for Government - $10
  - If pilot successful at top govt. hospital, national rollout intended
  - Also offered in 15 other countries including Bangladesh, Indonesia, Myanmar, Nepal, Pakistan and Vietnam

Sweden's Mölnlycke Healthcare: $1.5 billion global sales

- Wound Care, Consumables (drapes, gowns, masks)
  - Entered in 2012
  - Competes with 3M, Kimberly Clark, India's Romsons (~30% of 3M's prices)

Devices are Regulated as Drugs in India Today

- Federal regulations under “CDSCO”
  - Few limitations on what can be imported/sold
  - Foreign approvals from US FDA or EU’s CE accepted
    - Indian inventors currently at disadvantage on multiple counts
  - Many Indian states have their own FDA, in addition
- Device regulations discussed since 2005
  - 3 Indian ministries involved: Health, Electronics, Chemicals
  - Bill to be introduced in Parliament, open for public comment in Jan 2015
    - After bill becomes law, regulations may take a year
    - Amritt prediction: see final regulations in ~2016 or later
  - Foreign companies worry about surprises
    - Possible knee-jerk reactions by regulators
- **Takeaway:**
  - You will probably need third-party help in filing your first several approvals
  - The process is best handled by someone who specializes in India, rather than a multi-country service provider, who may not be familiar with processes that are not fully documented in India’s current system

Vast contrasts in quality of service

Apollo Hospitals

- Featured as Harvard Case Study
- Largest corporate hospital chain,
- 10,000 beds, 56 hospitals, 1,500 pharmacies
- Dr. Prathap C. Reddy, Founder, awarded India's 2nd highest civilian honor

General Hospital

- Not featured by Harvard
- Run by government
- Overcrowding, hygiene are issues

Photo: The Hindu

Many large, viable segments

Skim the wealthy cream or Approach the aspiring middle class

- Inpatient facilities
  - Private (for-profit, or foundations)
    - Global class, Corporate: ~100 high - end locations (5% beds)
      - Medanta, Apollo, Fortis, Asian Heart, Narayana Hrudulaya
    - ~500 medium sized legacy hospitals (15% of beds)
    - Thousands of specialty “nursing homes”
      - < 50 beds , 60% of beds
  - Government (tender); Free, 20 % of beds
    - Teaching, research hospitals (750+ beds)
    - State, District , Community (30 to 300 beds)
    - Autonomous government: Defense, Railways, Utility Companies
- Outpatient Doctor Clinics; > 1 million
- Emerging Home Care solutions

Legacy hospital from pre-independence days

Segmenting creatively can uncover profit

Intravenous Catheters ~ 300 million units; $75 million annual sales

Insight

Traditional Western Target:

The Rich

Margins are similar to those made in Western countries

- There is a willing hidden market niche within this latter population: ASPIRERS

Remaining Population:

NOT currently reached by new Western entrants

- Significant portion of remaining population willing to spend more than the base amount, but less than wealthy

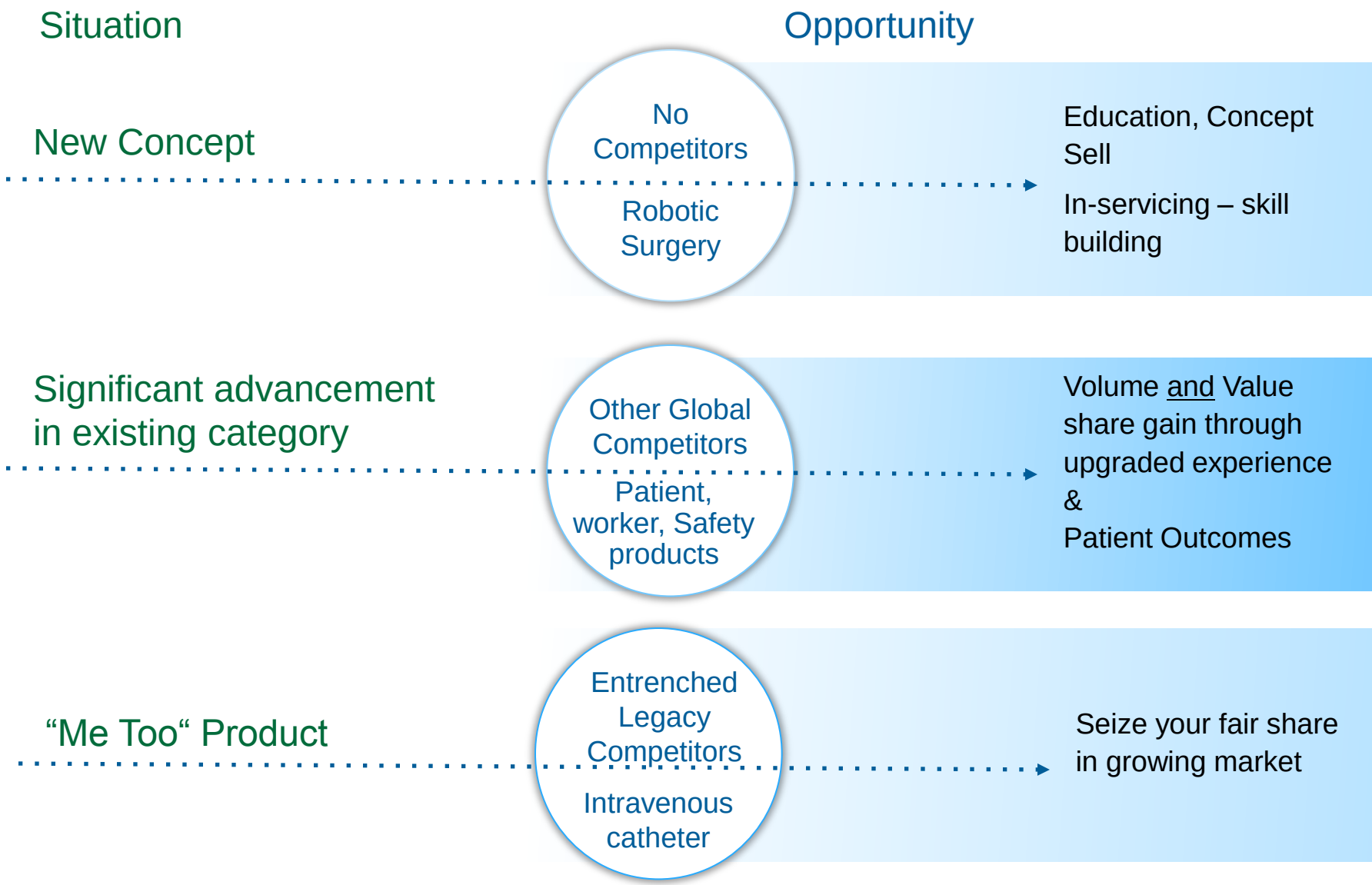
Aspirers

- Spend 60% premium for higher quality Western company IV Catheters (15% Vol, 40% Value)
- However, willing to spend a premium for higher, more consistent quality.

Remaining Population

- Spend 5_c for winged needle set
- Declining segment

“Mining” for Med-Tech Treasure in India



Distributors are fragmented

Scenario

- Hundreds of “mom-and-pop” regional or metro distributors
- A few claimed “national” distributors
  - Essentially those with stronger finances and ability to handle import licenses. National reach through network of “sub-distributors”
- Box Pushers, wholesalers, limited value added selling
- If your distributor sells your competitors’ products they are less inclined to promote / push yours

Concerns

- FCPA Compliance
- Disproportionately High Mark-ups
  - Slow share gain
- Transparency in pricing, margins
- Cross channel conflict

One Creative Amritt Solution

- ***Enter through Distributor…… and combine with a strategic partner***
  - Senior, experienced India-Domain experts, high strategic capability – on a “variable cost” basis
  - Augmented “translational” interface between Company and distributor
  - Custodian of Ethics, Compliance, culture
  - A ready “Sales and Marketing department”
    - Plan, propose, and execute demand generation activities
    - Distributor management, drive commitment to our brand
  - Possible advocacy to shape policy, create long term, multi stakeholder PPPs – positioning company as “knowledge partner”, to address large social health issues, while embedding select technologies as an integral part of the solution

Retrieved from Novartis (2009)

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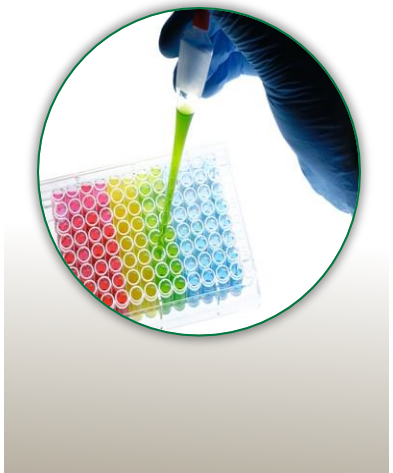


Engineers in India help Western device companies

"Captive" Engineering Centers for GE, Siemens, Philips, Covidien, etc.

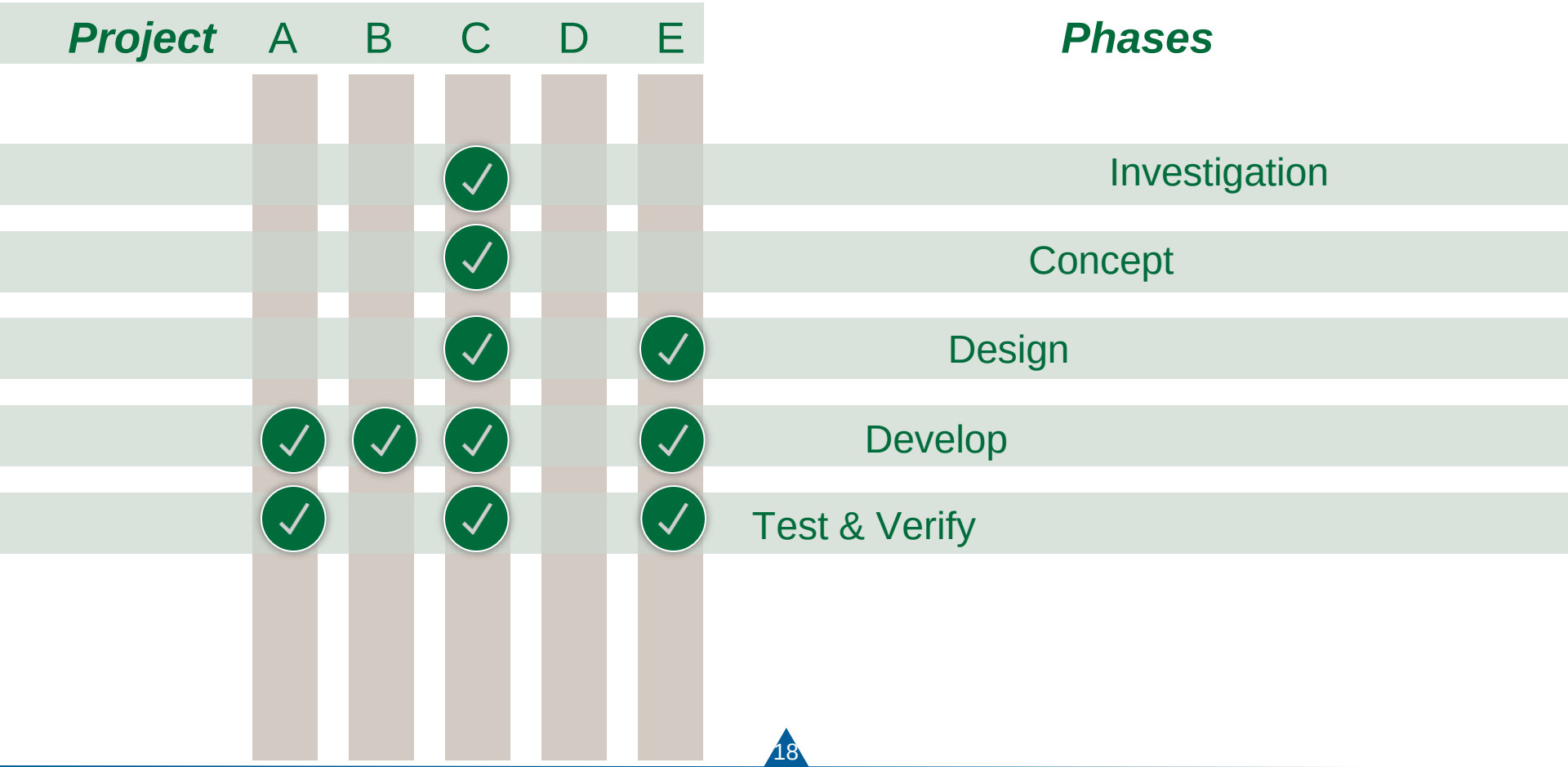
- GE Lullaby Baby Warmer, a good example
- Designed in and for India, sold in Europe as well
  - External "Engineering Service Providers"
  - For Product design, testing, sustaining engineering
- Clinical Trials of Devices in India
  - Can accelerate time to market in West
- IP and patents in cases above are owned by Western companies

Lullaby Baby Warmer

Selecting the portion of the development lifecycle you can offshore or outsource

Many companies start with offshoring or outsourcing design verification or analytical testing to India/China.

Over time they move upstream in the product development process lifecycle



Extend U.S. R&D team

(Release US team for higher value projects)

Why captive model selected

- Cost arbitrage
- Establish brand presence
- Improve Time-to-Market

Geographies considered

- Japan
- China
- India

Potential locations in India

- Bangalore
- Hyderabad
- Chennai

Project selection strategy

- Bangalore
- Hyderabad
- Chennai

Path to Captive R&D Center

- Established captive center from the beginning, but outsourced first to start process.
- Benefits of flexibility of outsource resulted in a hybrid model later

Company A Case Study

Gain R&D Footprint in Local Economy

(Outsource first – hybrid model later)

Why captive model selected

- Quick ramp to functionality
- Cost arbitrage
- (Later) Maintain some resource flexibility

Geographies considered

- Germany
- China
- Japan
- India

Potential locations in India

- Bangalore
- Hyderabad
- Delhi
- Gurgaon
- Pune

Project selection strategy

- Extension of US teams – Design & Test phases

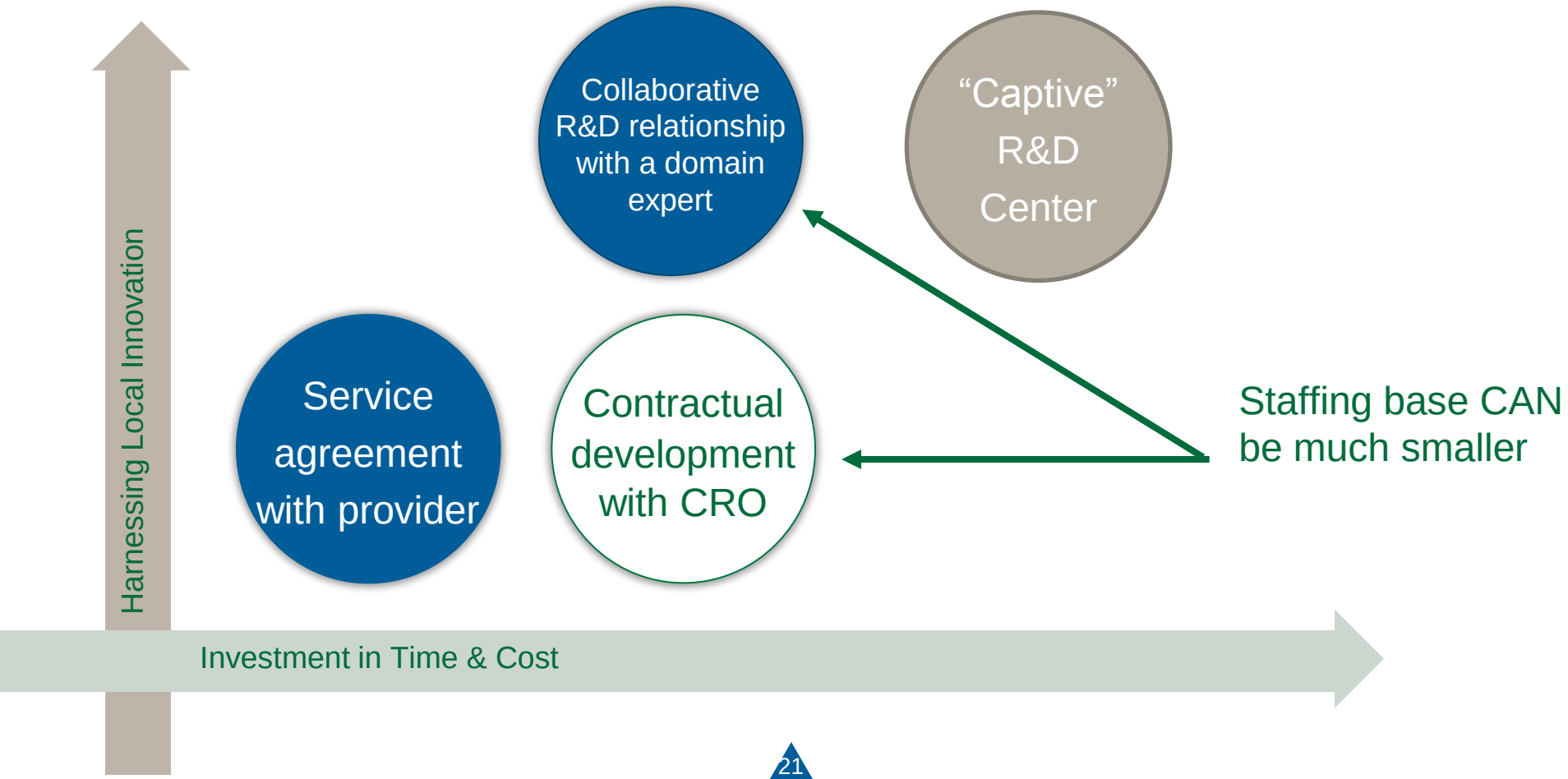
Path to Captive R&D Center

- Initially outsourced. Moved some work in-house later

Company R Case Study

Balancing Global Medical Device R&D Capabilities

Size and Access to Local Innovation



India: a Source of Innovation?

- Software talents driving some innovation
  - iPhone Apps, ERP integration, embedded capability
- “Frugal innovation” driven by local needs
  - Use models (pay per use, share, 24x7 operation)
  - Re-usable rather than disposable systems
  - Tele-diagnosis
    - Leapfrogging the landline
    - Fewer legal liability hassles
- A few venture-funded Indian startups address global markets from India
- In these cases patents/IP owned by Indian companies

Next Steps for Success in India

Send email to request:

Harvard Business Review article on
"*How U.S. Businesses Can Succeed in India in 2015*"

MedDevice Insights, December 2014:
Pot of Gold or Fool's Gold: Opportunities in India's Medical Device Ecosystem

Contact us for any questions, advice , guidance on entering,
on expanding into India's Med-Tech market,
on sourcing from India or
on using India's engineering talent

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