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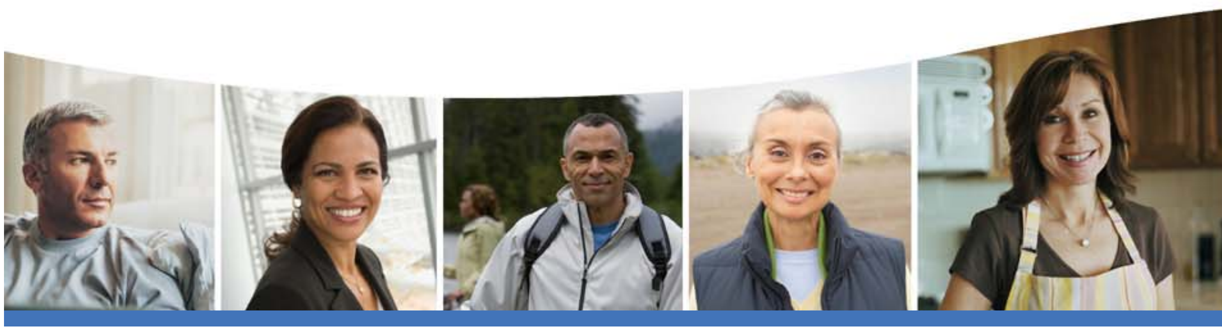
MICCAI 2009 Tutorial:
Medical Robotics and Computer Assisted Intervention

TECHNOLOGY TRANSFER

Simon DiMaio
20 September, 2009



Outline

- Personal background
- Company background
- Research at Intuitive
- The Challenge: bringing technology to market
- Collaborative research and outreach
- Case Studies

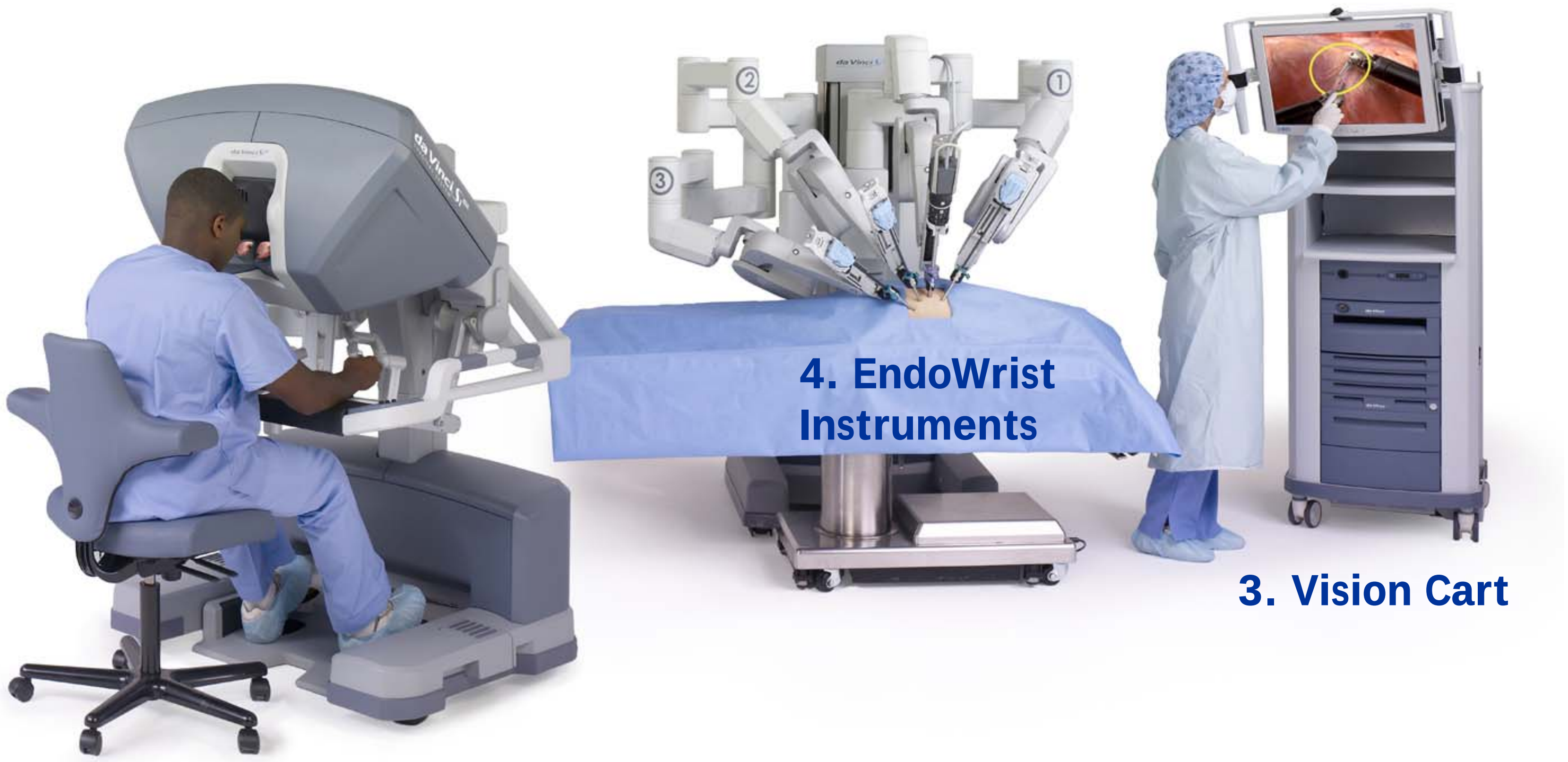
Personal Background

- B.Sc. (EE), University of Cape Town, South Africa
- M.A.Sc. & Ph.D., University of British Columbia, Canada
  - *Robotics and control systems*
  - *Needle insertion modelling and steering*
- Surgical Planning Laboratory, Harvard Medical School
  - *MRI-compatible robotics*
  - *Neuro-fiberscope navigation*
  - *Multi-modality image guidance*
- Intuitive Surgical (2007)
  - *Applied Research Group*
  - *6 researchers (ME, EE, CS, Vision)*

Company Background

- Chronology:
  - *1995, Intuitive Surgical founded.*
  - *1999, da Vinci Surgical System introduced.*
  - *2000, FDA clearance for general laparoscopic surgery.*
  - *2000, Initial Public Offering*
  - *2006, da Vinci S introduced.*
  - *2009, da Vinci Si introduced.*
- *da Vinci* Application areas:
  - *cardiac, urology, gynecologic, pediatric, and general surgery.*
- Installed sites: >900 academic and community hospitals
- Installed systems: >1100
- Employees: >1100

da Vinci System Description



Applied Research @ Intuitive

- Applied? "Application of knowledge to address a specific need."
- Six-person research team (ME, EE, SW, Vision).
- Horizon: 2-7 years from product.
- Themes:
  - *User interfaces*
  - *Imaging and vision systems*
  - *Simulation and training*
  - *New architectures*
- External Research Collaborations:
  - *Johns Hopkins University*
  - *Imperial College, London*
  - *Harvard University*
  - *Vanderbilt, etc…*

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Bringing Technology to Market

From Lab to Operating Room

University Centers

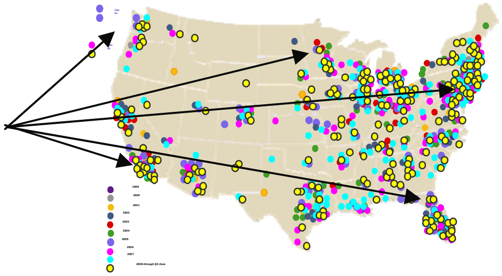
- Image Acquisition
- Machine Vision
- Mechanism Design

Innovation requires enormously cross-disciplinary collaboration

Research/Teaching Hospital

Challenge: Collaboration and demonstrating efficacy in the clinical environment

Healthcare System



Challenge: Adoption of innovative clinical solutions across healthcare system

Slide Acknowledgement: Gary Guthart

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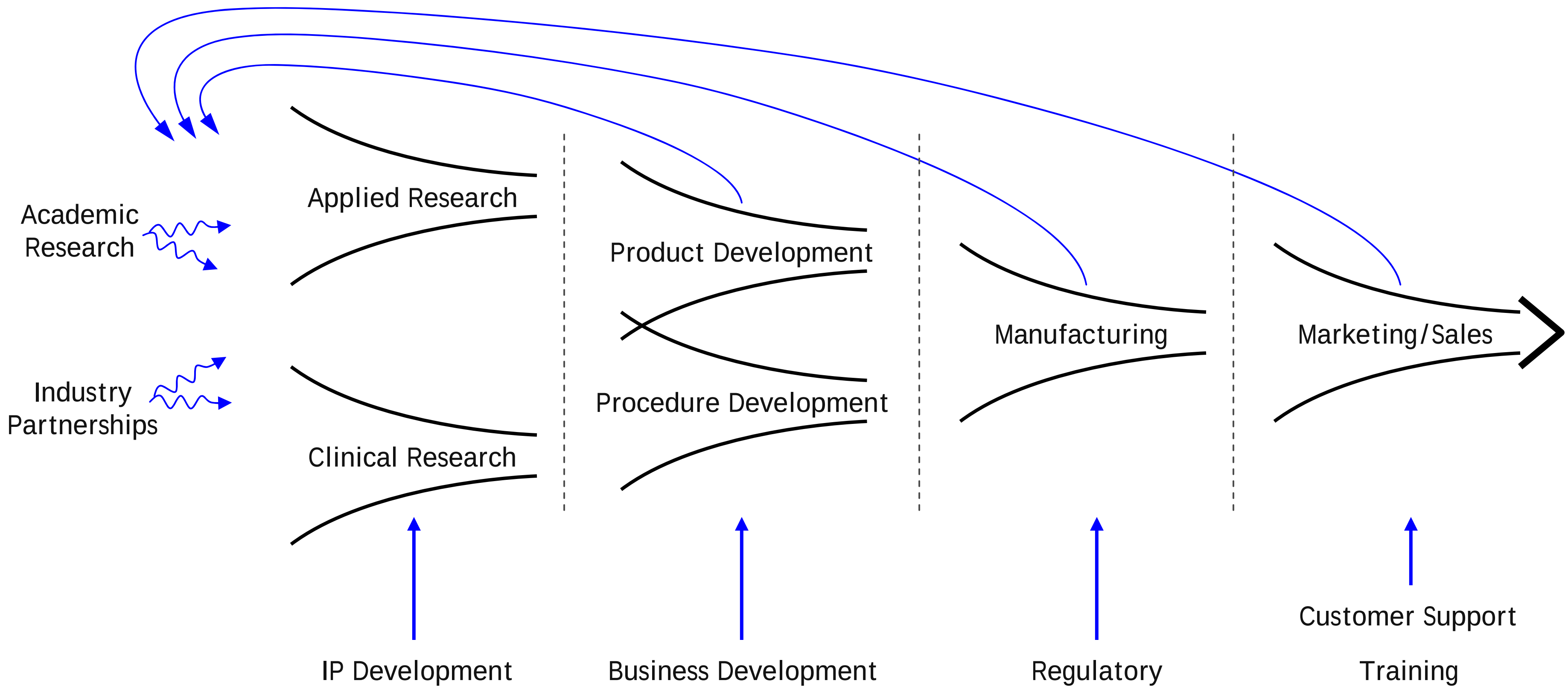
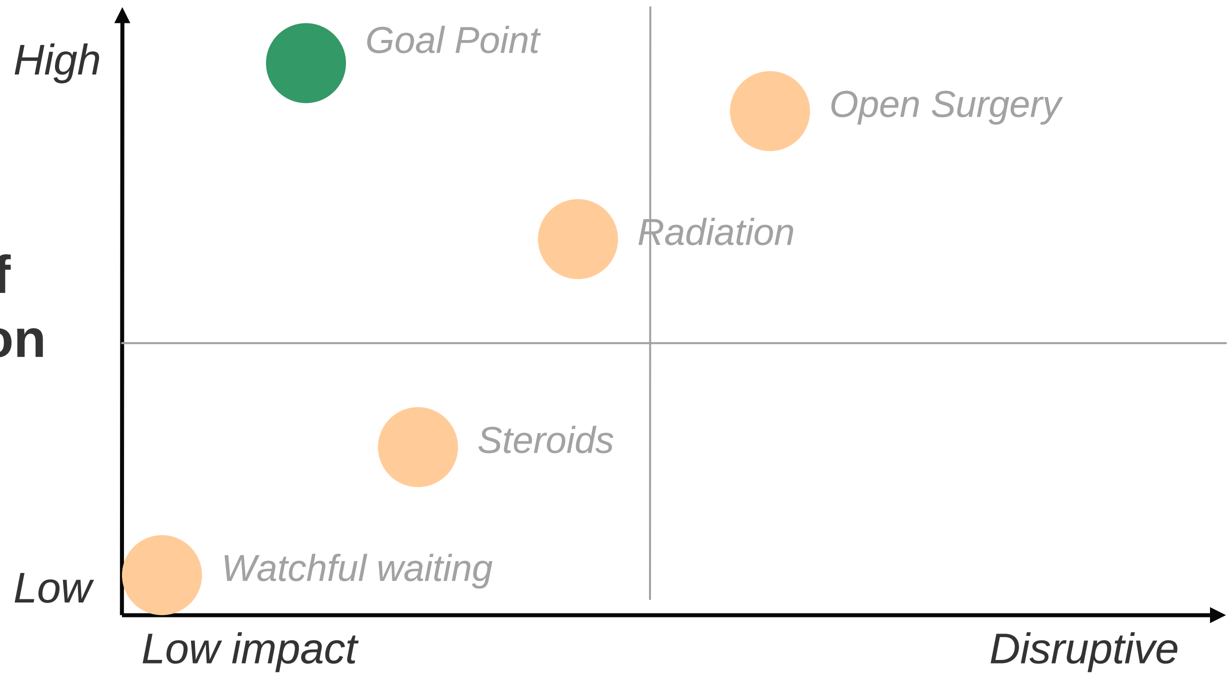
Bringing Technology to Market: Inside ISI (a gross simplification)



Coordination: A Common Value System

- **The value system:**
  - *Patient value* = *efficacy/invasiveness^2*
  - *Surgeon value* = *patient value + repeatable, teachable & reliable*
  - *Hospital value* = *surgeon value + economic benefits*
- **Product Priorities:**
  - *Safety* – *for patients, hospital staff, employees*
  - *Efficacy* – *"it works, all the time"*
  - *Ease-of-use* – *easy to learn, performance easy to access*
  - *Economics* – *makes sense for hospital, payer and ISI*
  - *Develop fast* – *get on with it!*

Example Value Proposition – Prostate Cancer



Efficacy of Intervention

Cancer removal %

Invasiveness of Intervention

- **Time to full recovery (pain, function)**
- **Blood loss**

Slide Acknowledgement: Dr. D. Murphy

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Research Challenges

- The challenge appears to be less about figuring out what technology to work on.
  - *However, with limited resources, we need to be selective.*
- How to deliver computer-aided interventions faster and cheaper?
  - *There are very few profitable companies in this space.*
  - *At ISI, profitability required a ~$500M investment!*
  - *Financially stressed healthcare system = conservative funding.*
  - *Systems solutions are technologically complex.*
  - *Diverse regulatory standards = strenuous and time consuming.*

Complexity

- A *da Vinci* system is composed of roughly 10,000 individual components (counting down to resistors).
- There are ~ 1.4 million lines of embedded run-time code; and this for a system that is not autonomous.
- A typical software verification run will comprise of ~40,000 test cases.
- The formally maintained design history file is >10,000 pages of documentation.

Slide Acknowledgement: Gary Guthart

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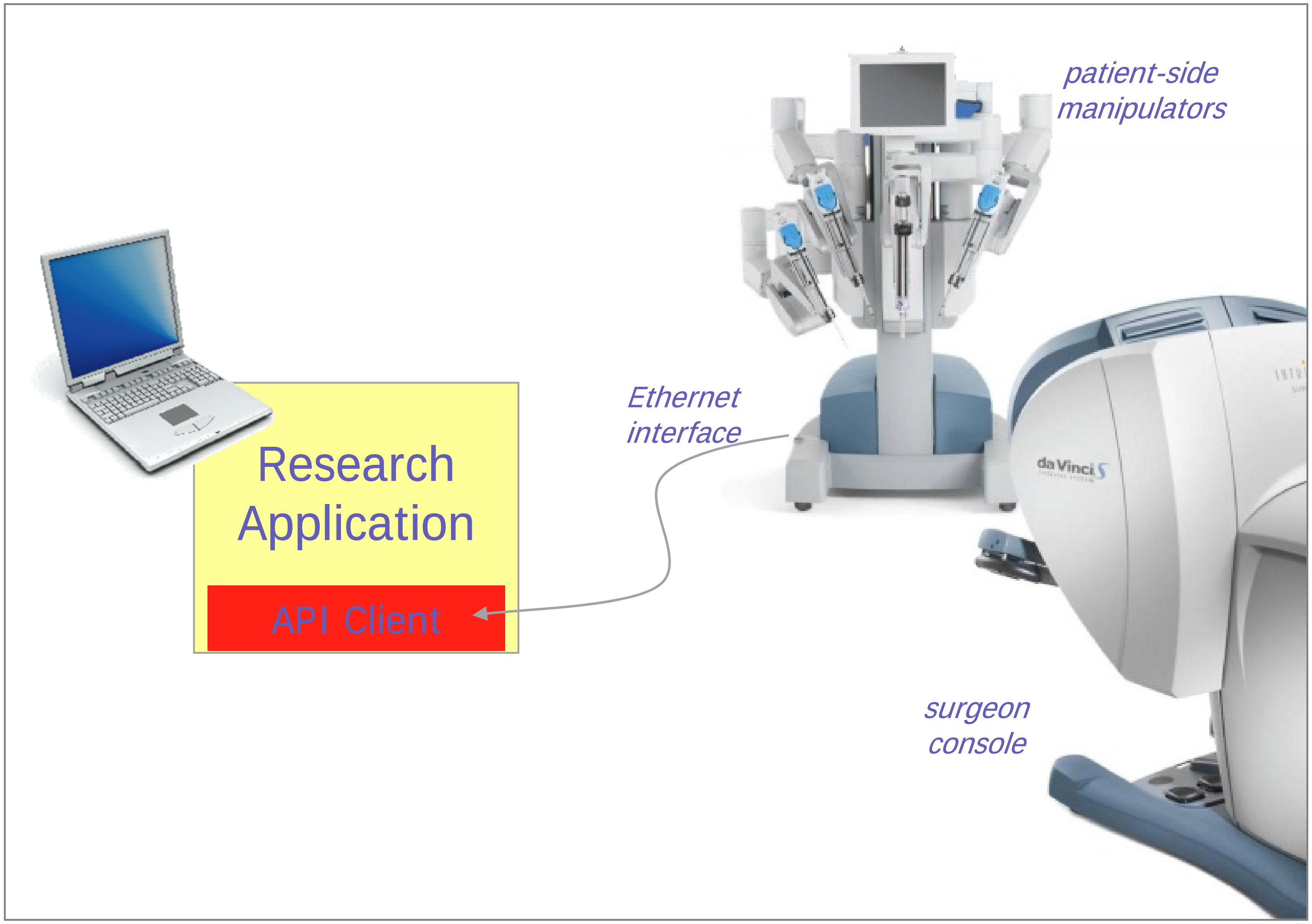
University Outreach and Collaboration

- Engagement mechanisms:
  - *da Vinci research interface*
  - *Grant collaborations*
  - *Hosted Internships*
  - *Conference awards*
  - *Fellowships and seed funding*

The *da Vinci* Research Interface



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The *da Vinci* Research Interface

- *da Vinci* and *da Vinci S* support
- Ethernet interface, TCP/IP protocol
- Output only (except for interface control)
- Manipulator data stream
  - *MTM-L, MTM-R, PSM1, PSM2, PSM3, ECM*
  - *10-100Hz update rate*
- User interface events
- Approved for human use

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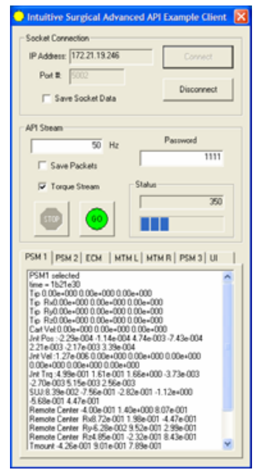
da Vinci **API: Example Applications**

Data Capture



Analysis

- *system knowledge / understanding*
- *task & skills analysis*
- *device development*
- *procedure development*

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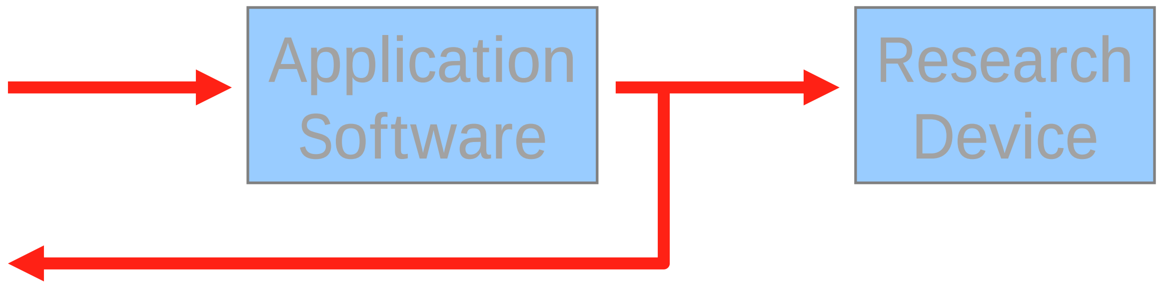
da Vinci API: Example Applications



- *user interface development*
- *image guidance*
- *simulation and training*

The da Vinci Research Interface

- Why is this interface not open?
  - *confidentiality,*
  - *safety,*
  - *support resources,*
  - *competitive advantage.*
- The API Agreement
  - *terms of use,*
  - *restrictions of use,*
  - *confidentiality,*
  - *limitations of liability,*
  - *agreed rights to intellectual property.*

Establishing a Research Collaboration with ISI

- Initiate an API Agreement
- Statement of Work
- Key criteria:
  - *Research Match*
  - *Technical Strength*
  - *Clinical Strength*
  - *Communication*

da Vinci API: Further Information

- See information and references in our paper:
  - *http://hdl.handle.net/10380/1464*
- Contact:
  - *Brandon Itkowitz (brandon.itkowitz@intusurg.com)*
  - *Simon DiMaio (simon.dimaio@intusurg.com)*
  - *Chris Hasser (chris.hasser@intusurg.com)*
- Intuitive Research website coming soon

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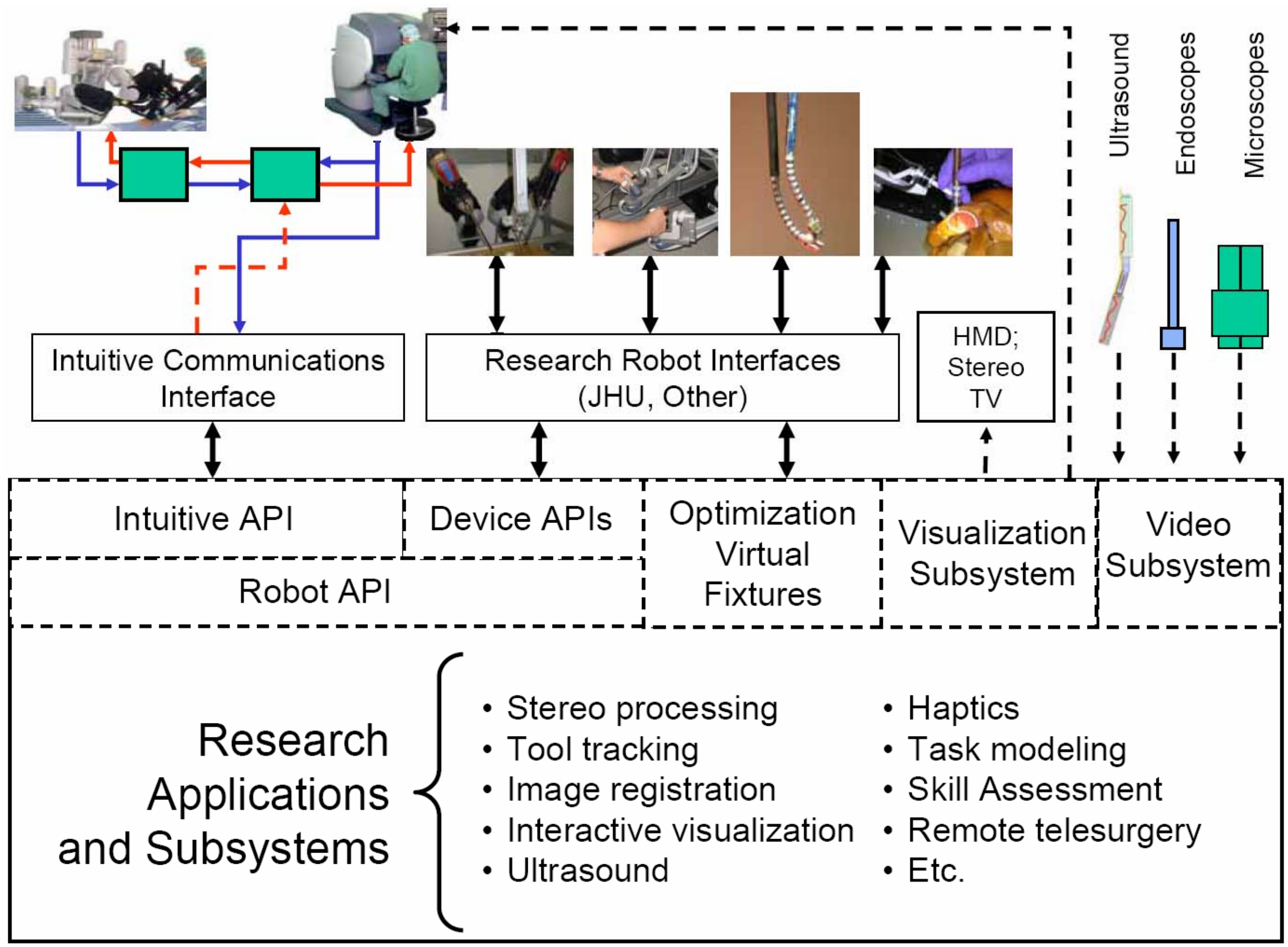
Case Study: The Surgical Assistant Workstation

- NSF ERC Supplement (PI: Russ Taylor)
- **What is it?**
  - *An open-source medical robotics framework.*
  - *Infrastructure glue.*
  - *A toolkit for integrating hardware and software modules.*
  - *A multi-institutional collaboration.*
- **Rationale:**
  - *Medical robotics systems are complex.*
  - *Research groups typically develop component technologies, not entire systems.*
  - *Need a common system development framework.*

Surgical Assistant Workstation (SAW)

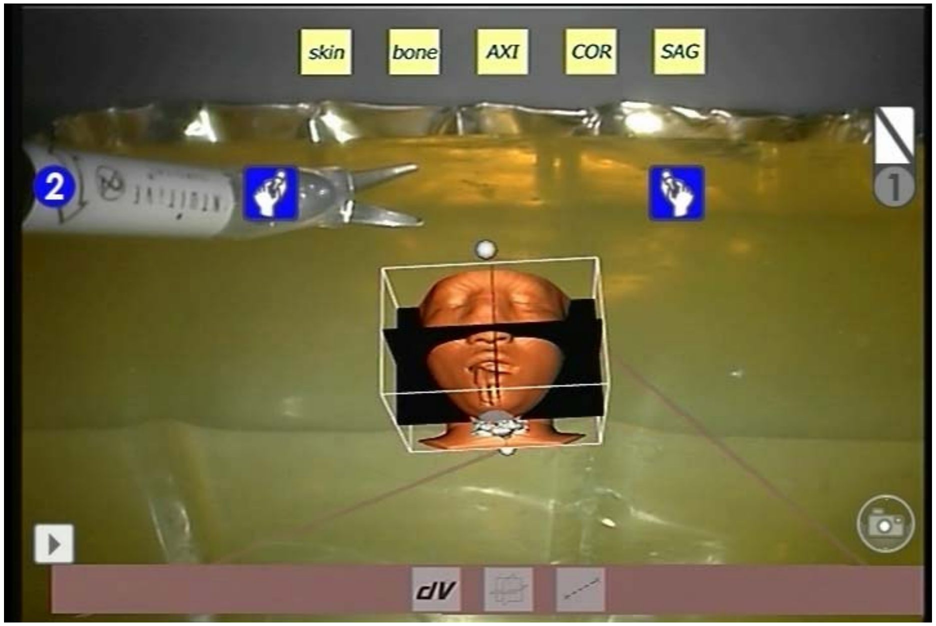


SAW: Sample Use Cases

- Image Guidance:
  da Vinci with medical image overlay
- Image Guidance:
  da Vinci with laparoscopic ultrasound instrument
- Haptic Guidance:
  virtual fixtures
- Research Hardware:
  prototype devices (e.g., JHU Snake Robot)

SAW Use Cases: *da Vinci* Image Overlay

- *da Vinci with medical image overlay*
- *da Vinci with laparoscopic ultrasound instrument*



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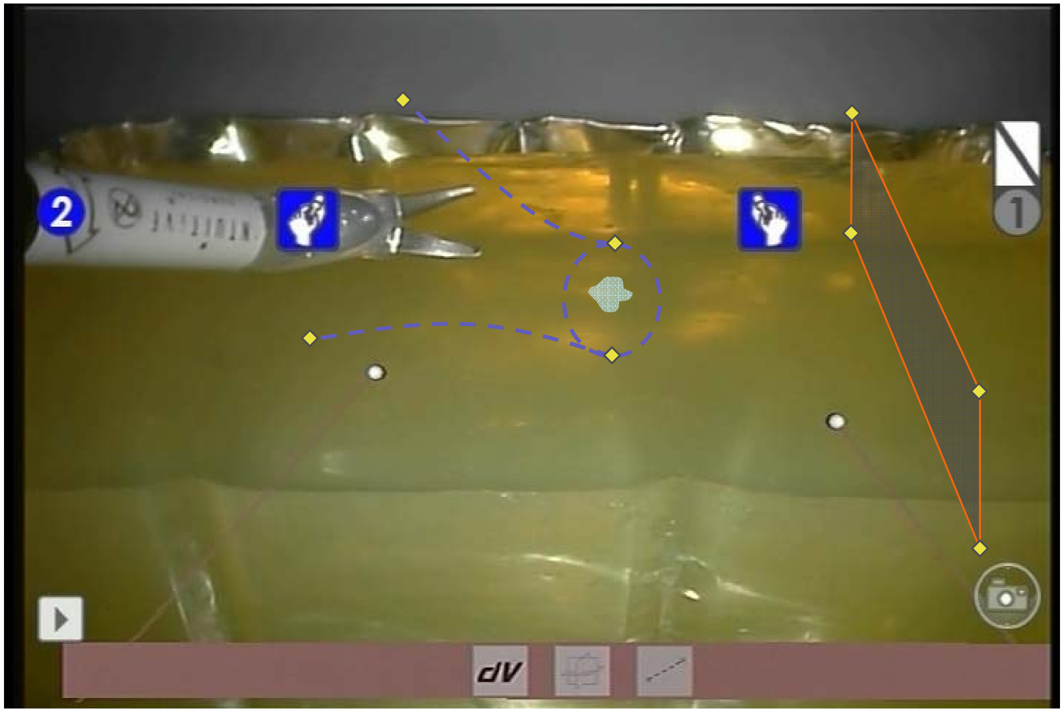
SAW Use Cases: Virtual Fixtures

- *Interactive placement of virtual fixture geometry:*
  - *“forbidden regions” or “guidance fixtures”*



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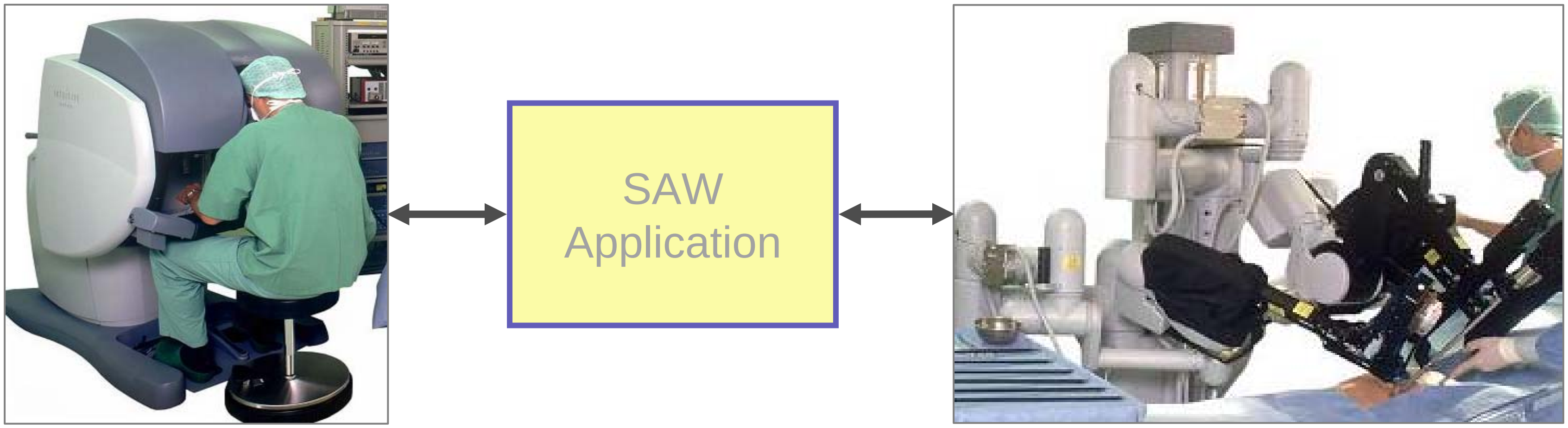
Use Case: Hardware Prototyping



Use Case: Hardware Prototyping

SAW Application

JHU Snake Robot

Use Case: Hardware Prototyping

PHANToM Omni

SAW Application

Use Case: Hardware Prototyping

PHANToM Omni

SAW Application

JHU Snake Robot

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SAW Framework: Summary

- A toolbox for rapid prototyping.
- Enables faster innovation and development.
- Enables technology transfer to commercial systems.
- Intuitive Surgical's role:
  - *Interface between da Vinci and SAW (a SAW plug-in under separate license).*
  - *Develop research use cases.*
- Looking forward:
  - *Multi-institutional adoption & development.*
  - *A common interface to commercial systems.*

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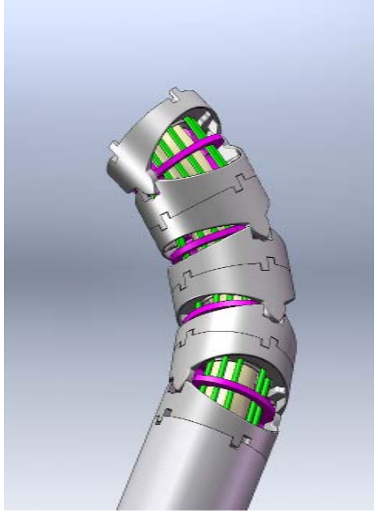
Case Study: *da Vinci* Ultrasound

- NIH STTR Phase I and II
- Specific Aims:
  1. *Develop functional capabilities required for LUS-assisted robotic surgery.*
  2. *Produce an Integrated Robotic System for LUS-Assisted Hepatic Surgery.*
  3. *Evaluate the effectiveness of the overall system and specific functions for hepatic surgery.*
- Rationale:
  - *Subsurface imaging.*
  - *Liver staging, assessment, and biopsy.*
  - *Image guidance for liver tumor ablation.*
  - *Image guidance for liver resection.*

da Vinci Ultrasound: Instruments



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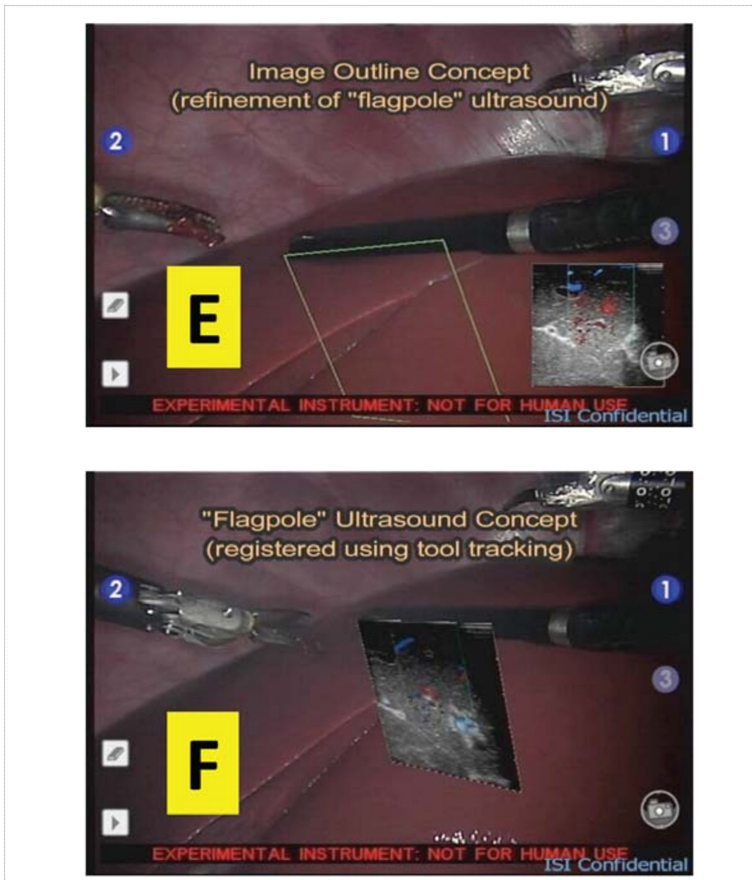
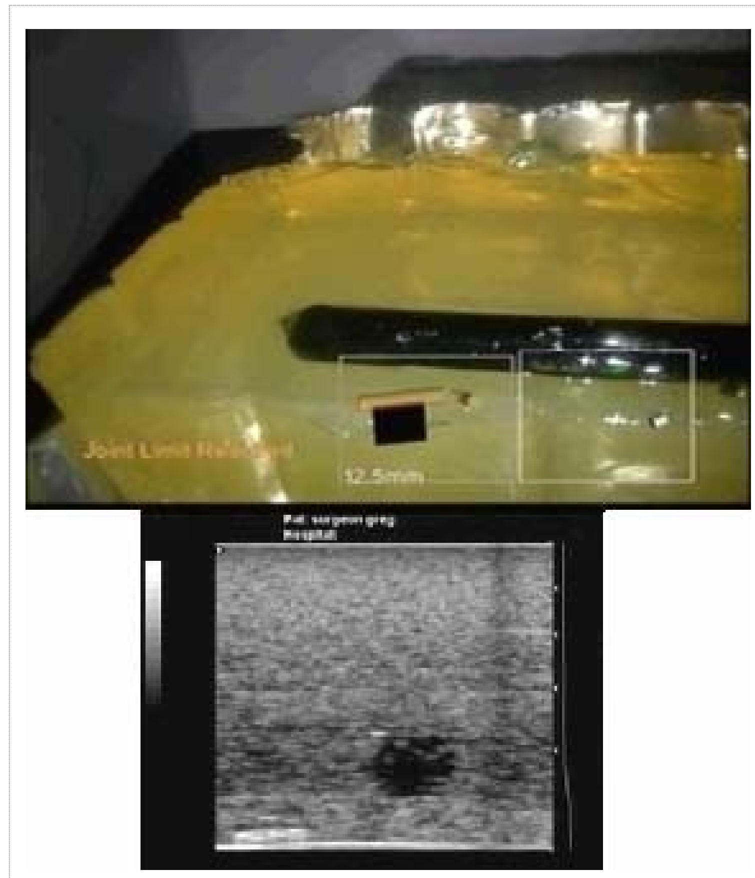
da Vinci Ultrasound: User Interface

- Leverages the Surgical Assistant Workstation:





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da Vinci Ultrasound: Surgeon Evaluation Study

Johns Hopkins University
IRB Approved
HOMEWOOD IRB

- Compare da Vinci ultrasound versus hand-held LUS.
- Focus on liver applications.
- Tasks:
  - *lesion finding,*
  - *biopsy,*
  - *liver exploration.*
- Johns Hopkins IRB approved study.
  - *5 subject studies completed to-date.*
  - *In vivo and phantom studies at Intuitive Surgical, California.*
  - *Phantom studies at Johns Hopkins University.*

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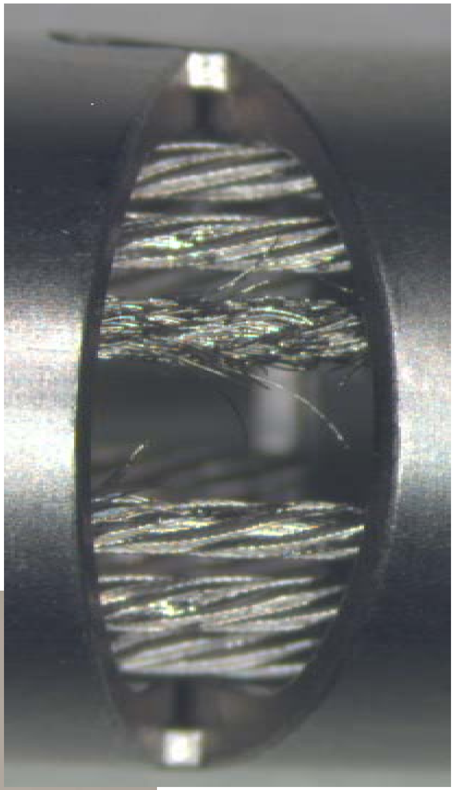
Ultrasound: Product Development Challenges

- Sterilization
- Instrument Diameter
- Cost model



Conclusions

- Computer-aided interventions are in their infancy.
- New technologies: imaging, vision, robotic mechanisms, tissue specific marking and tissue manipulation technologies need to converge to make an impact in clinical practice.
- Highly integrated/cross-functional academic teams including both engineering disciplines and clinical visionaries are key to integration.
- We need tightly integrated medical schools/academic centers and industrial developers that allow a fast clinical test loop.
- Applied research support by industry, with mechanisms for academic outreach and technology transfer.

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Thank You