

Embracing Innovation: The Process of Research & Publication in Practice

Karol A Gutowski, MD, FACS

The Aesthetic Meeting 2014

BUILDING THE BRIDGE BETWEEN SCIENCE AND ART

San Francisco April 24–29 Moscone Center



TO ADD

- How to evaluate a new product
 - Efficacy
 - Cost (use real company “estimates”)
 - Practice incorporation
- Quill experience
- Rep calling office asking about new technology
- Financial analysis
 - Case studies
 - Eval a product or device
 - Use biomed student

Disclosures

RTI Surgical - Advisor

Suneva Medical - Instructor

Angiotech/Surgical Specialties - Advisory Board

Viora - Nonpaid Speaker & Investigator

Learning Objectives

- Understand the innovation cycle
- Resources needed to innovate
- Industry relationships & partnerships
- Regulatory issues (HIPPA, IRB)
- Presentation & publication
- Common pitfalls

General Concepts

- Scientific approach to innovation
- Ask the question
- Set up the study
- Do the study
- Spread the news!
- Consult - Contribute

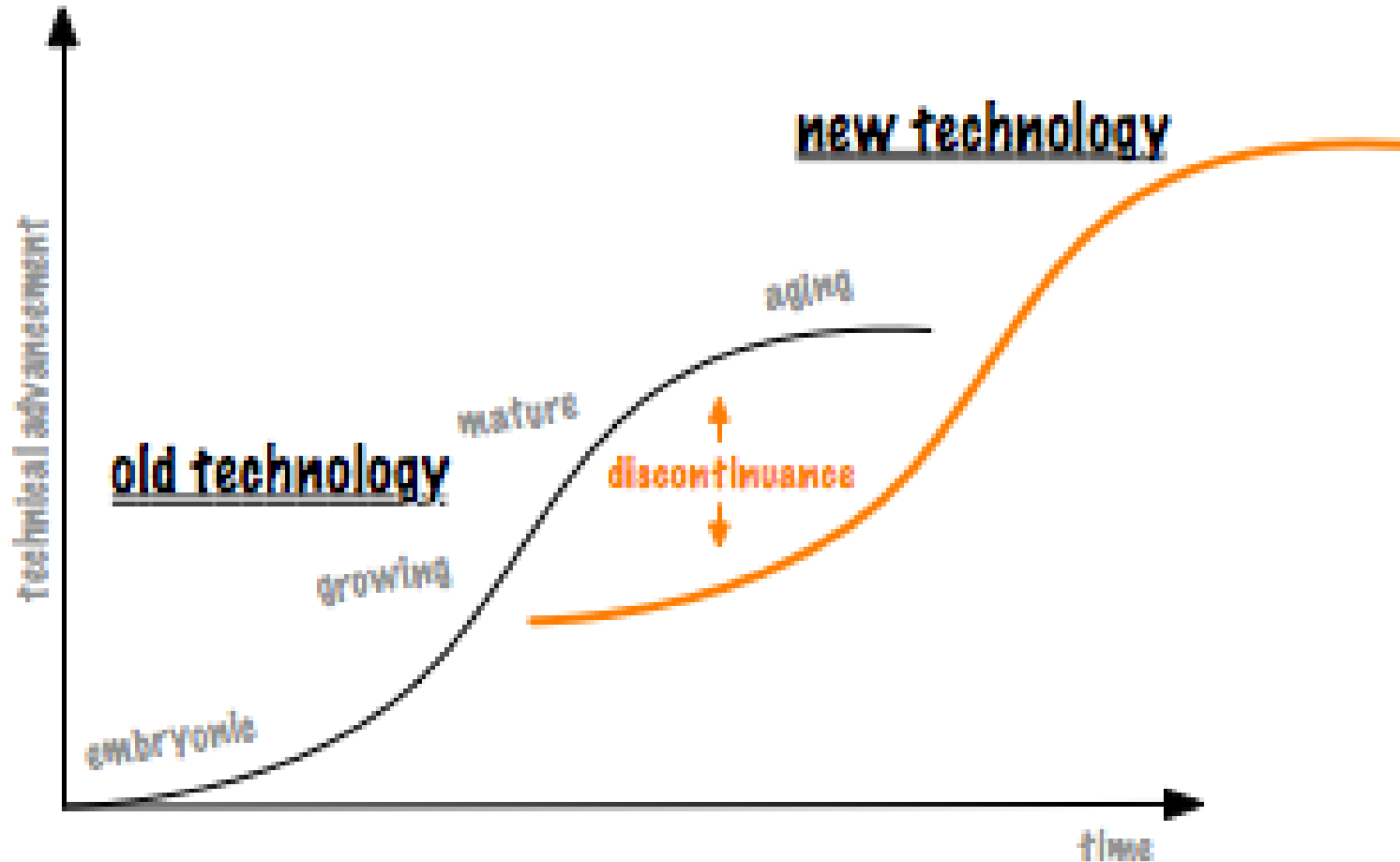
The “Hype Cycle”



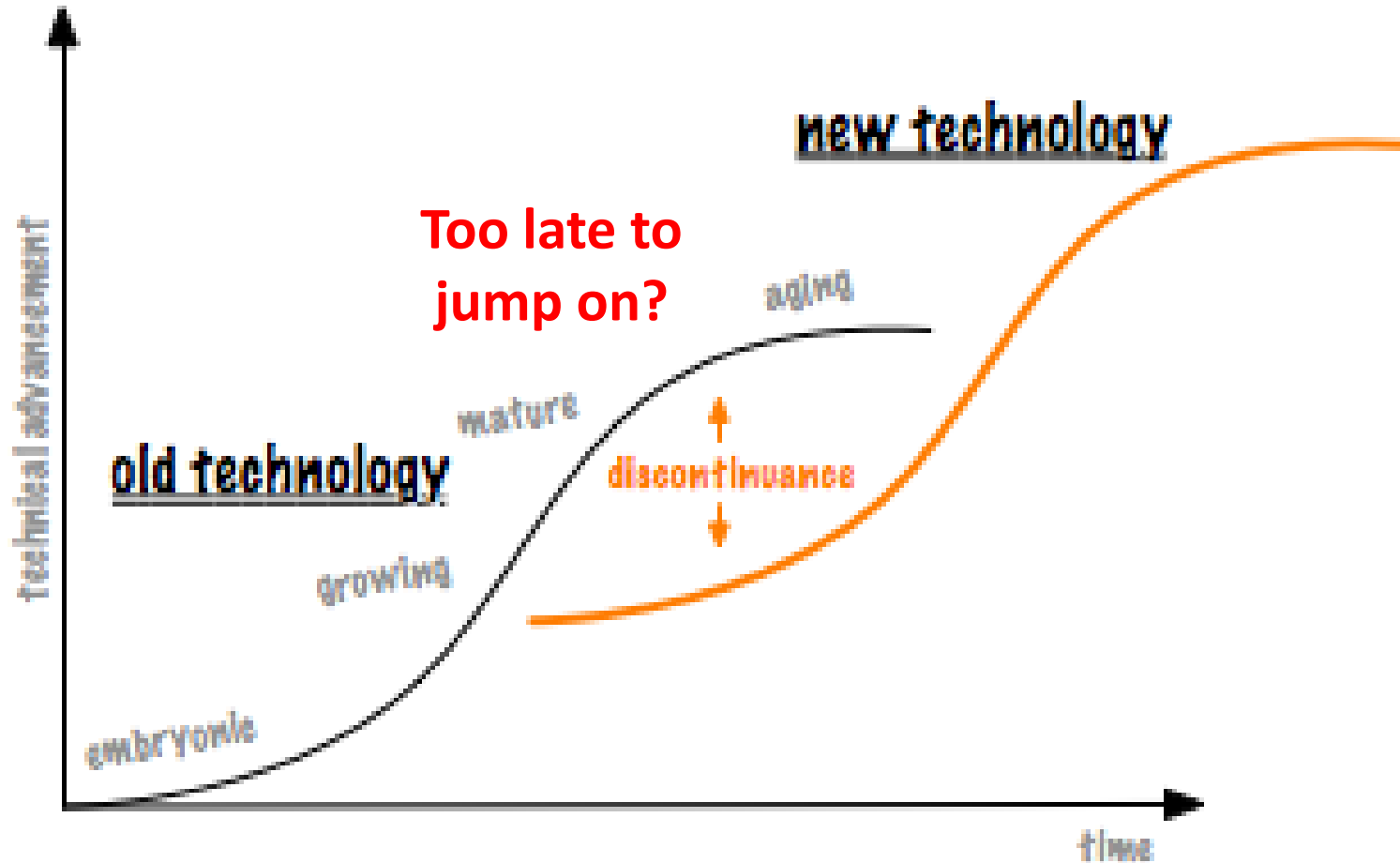
The “Hype Cycle”



Technology Overlap & Overtake

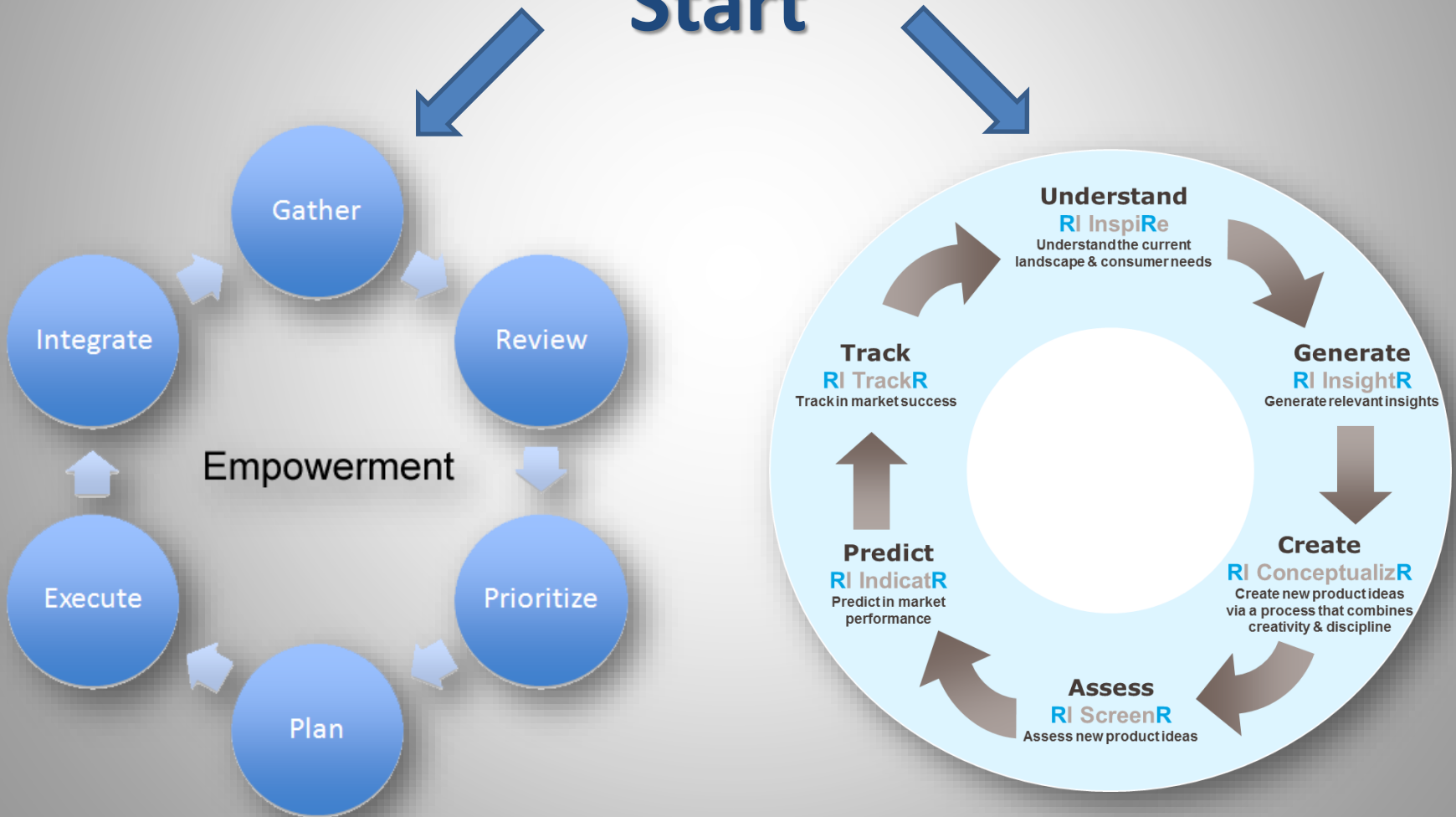


Technology Overlap & Overtake



Innovation Cycles

Start



Innovation in Plastic Surgery

- Not limited to academic practice
- Many “non-academic” innovators
- Aesthetic treatments ideal for private practice
- Most ASAPs inovators are not “academic”



Ways to Get Started

- What do I do well?
- What don't I do well?
- What is an unmet need?
- What is the competition doing?
- What are my patient's asking for?
- Mega-trends vs micro-trends

Time & Resources

Industry Site Assessment

- Your clinical volume
- Past industry-sponsored studies
- Clinical staff & experience
- Methods for patient recruitment
- Equipment available
- Space available
- IRB

Potential Site Questionnaire
Allergan Confidential

Please complete the form in **BLOCK CAPITALS** and return
Should you wish to speak with someone regarding the contents of this survey,
please call **Sarah Darmot: 714-246-3849**

Salutation: Dr Prof Mr Mrs Ms Other _____

KAROL GUTOWSKI

First Name of Principal Investigator: **KAROL** Last Name of Principal Investigator: **GUTOWSKI**
 Institution/Practice Name: **OHIO STATE UNIVERSITY** Type of Institution (e.g., hospital, university, private clinic): **UNIVERSITY**
 Address: **915 OLENTANGY ROAD, SUITE 2140** Country: **USA**
 Town / City: **COLUMBUS** Zip Code/Postal Code: **43210**
 Business Phone Number: **714-246-3849** Business Fax Number: **614-293-3381**
 Email Address: **KAROL.GUTOWSKI@OSUMC.EDU**

Area of Specialty (check all that apply): Dermatology Ophthalmology Plastic Surgery

INVESTIGATOR'S RESEARCH INTEREST AND PARTICIPATION

Specific areas of clinical research interest and experience (e.g. rotacea, psoriasis, acne, fillers):
AESTHETIC BREAST SURGERY, BREAST IMPLANTS, BODY CONTOURING, LIPOSUCTION, SKIN TREATMENTS INCLUDING INJECTABLE PRODUCTS (NEUROTOXINS, FILLERS) LASERS, ETC.
OUR GROUP ALSO HAS A FOCUS ON BREAST RECONSTRUCTION, MIGRAINE HEADACHE TREATMENT AND ABDOMINAL WALL RECONSTRUCTION.

Have you participated in Industry-sponsored (medical and/or aesthetic) clinical studies before? Yes No

Have you conducted industry-sponsored clinical studies conducted at your site? YES

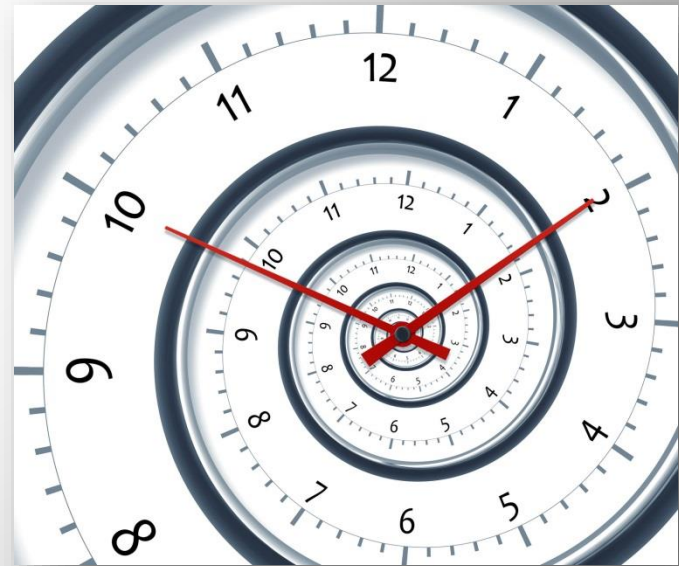
*If yes, specify approximate study dates, study titles, number of patients enrolled the table below:
CLINICAL STUDY OF RADIOFREQUENCY SKIN TIGHTENING - IN PROGRESS

Approx. study date (yr) (start/end or ongoing)	Indication/ Study Title	Allergan-Sponsored (Y/N)	# Target patients to be enrolled at your site	# patients enrolled
2014	RADIOFREQUENCY SKIN TIGHTENING	NO	15	ON GOING

MA Site Questionnaire 05/EN13 Page 1 of 7

Time Commitment

- Your time commitment
- Staff training
 - Protocols
 - Documentation
- Staff time obligations
 - Consents
 - Follow up
 - Regulatory issues
- Workflow redesign



Partnerships & Relationships

Innovation Partnerships

- Academic centers
 - Identify collaborator
 - Statistical and analytic support
 - Resident support
- Colleagues
 - Plastic surgeons
 - Other specialties
- Do not need to be local
- Define roles and responsibilities early

Project Assistants

- Undergraduate students
- Medical students
- Residents & fellows
- Nurses & physician assistants

Check background

Industry Partners

- Build relationships
- Use the product
- Discuss ideas
- Look for improvements
- Ask for resources

Proceed with caution

Avoid Pitfalls

- Disclosures
- Legal agreements
- Conflict of interest
- Intellectual property
- Confidentiality agreements

Maintain your ethics

Innovation & Research: IRBs, HIPPA, Informed Consent

Is Innovation Considered Research?

- Fine line between trying something new and conducting human research
- **Research is:**
 - Testing of drugs, devices, or products
 - Data from surveys, interviews, observation
 - Medical records
 - Bodily materials, such as cells, blood, tissues, when linked to specific individuals
- May need IRB

Role of IRB

- Protect rights & welfare of research patients
- Monitor between patient and physician
- Can suspend or terminate research
- Help researcher
 - Decrease risk
 - Improve study design



Do I Need IRB Approval for

- Chart reviews?
- Pulling data from my database?
- Studies I think are minimal risk?

YES



CONSORTIUM OF
INDEPENDENT REVIEW BOARDS

Avoid the IRB Pitfalls

- Play by the rules
 - Ask for guidance from IRB
 - Review every submission & revision yourself
- If you don't
 - Not get published
 - Be sanctioned
 - Shut down research

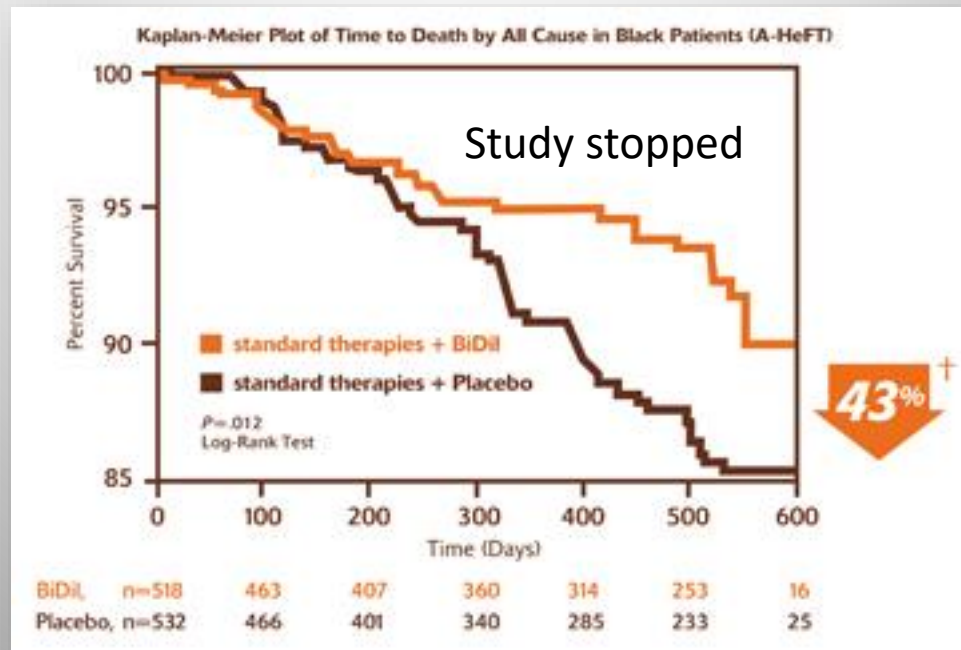


Multicenter Trials & Local IRBs

- Expect
 - Paperwork revisions
 - Duplication of efforts
 - Inconsistencies in recommendations
- Therefore, be
 - Proactive
 - Patient
 - Prepared for long timeline

Data Safety Monitoring Boards

- Purpose: Subject safety
- Used by industry and NIH sponsored studies
- Increasingly required for investigator initiated studies



Waiving Requirement for Informed Consent

- Research involves no more than minimal risk
- Waiver will not adversely affect the rights or welfare of the subjects
- Research could not be practicably carried out without the waiver
- Subjects will be provided with pertinent information after participation

Informed Consent

- Provide summary page
- 6th to 8th grade reading level
- Short sentences and paragraphs
- Use of Question & Answer format (FAQs)
- Increase font size, use bold, italics, color
- Use of bullet points
- Cite major risks, append others
- Use of tables for risks
- Use graphics
- Don't overestimate benefits or, underestimate risks

HIPPA

- Maintain study subject confidentiality
- Requires well thought out plan to gather data
- Review HIPPA guidelines
- Document all researchers HIPPA training



HIPAA
Compliance

Medical Records & Database Research

- If the **intent** is to collect data to answer a question that may develop or contribute to general knowledge, the project is probably research
- Rule of Thumb: If the intent is to publish the data or present it at a professional conference, the activities probably constitute research

Preparatory to Research

- Activities that can be performed without HIPAA authorization:
 - The development of research questions
 - The determination of study feasibility (available number and eligibility of potential study participants)
 - The development of inclusion and exclusion criteria
 - The determination of eligibility for study participation of individual potential subjects
- Preparatory Research Certifications may need be filed with institution Privacy Officer

Databases

- Use of database information can constitute human subjects research
- Databases created for clinical purposes (even if they may be used at some point to answer a research question) do not require IRB review but must be registered with HIPAA Privacy Officer
- Databases created for research require IRB review & registration with HIPAA Privacy Officer

What's Coming Next?

- Clinical trial registration
 - Government
 - Publishers
- Trial standardization
 - CONSORT Statement



The screenshot shows the ClinicalTrials.gov website. At the top, the logo reads "ClinicalTrials.gov" with the tagline "A service of the U.S. National Institutes of Health". Navigation links for "Home", "Search", "Study Topics", and "Background" are visible. A search bar is present on the right. The main content area includes a descriptive paragraph about the registry, followed by three sections: "Search for Clinical Trials" (with a sub-header and a paragraph stating 44,414 trials in 150 countries), "Investigator Instructions" (with a sub-header and a paragraph about registration instructions), and "Background Information" (with a sub-header and a paragraph about learning more). A right-hand sidebar contains "Background Information" links (Understanding Clinical Trials, What's New, Glossary) and "Study Topics" links (List by Condition, List by Drug Intervention, List by Sponsor, List by Location). The footer contains logos for NLM, NIH, and the U.S. Department of Health & Human Services, along with a list of website policies.



Avoiding Pitfalls

- Have a hypothesis
- Do the literature search
- Try a pilot study
- Determine sufficient sample size
- Measurable outcomes
- Overestimate time and resources needed
- Proper documentation and informed consent
- Watch for conflicts of interest

Getting Started

Know the Background

- Literature search
 - Was this already done?
 - What knowledge is missing?
 - Is the data current and applicable?
- Who is the competition?
- Ask to see industry (internal) data
- Talk with industry researches & scientific team

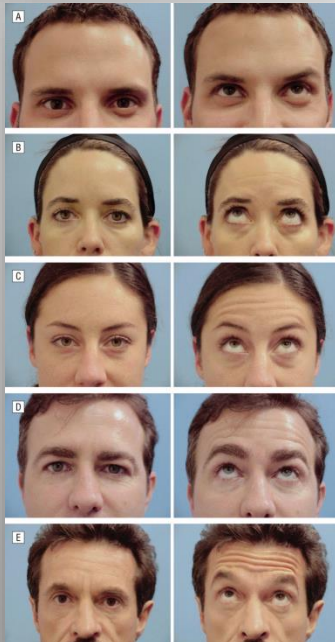
Design the Project

- Topic/research question
- Hypotheses
- Patient population
- Study design
- Data collection/instruments
- Analysis
- Funding sources
- Dissemination of study findings

Useful Tools

- Patient database
- Validated survey & assessment instruments
 - Wrinkle reduction scale
- Standardized outcomes tools
 - Breast-Q
 - Face-Q
- Standardized imaging & analysis
- Statistical support
 - Underpowered studies
 - Objective comparisons

Assessment Scales



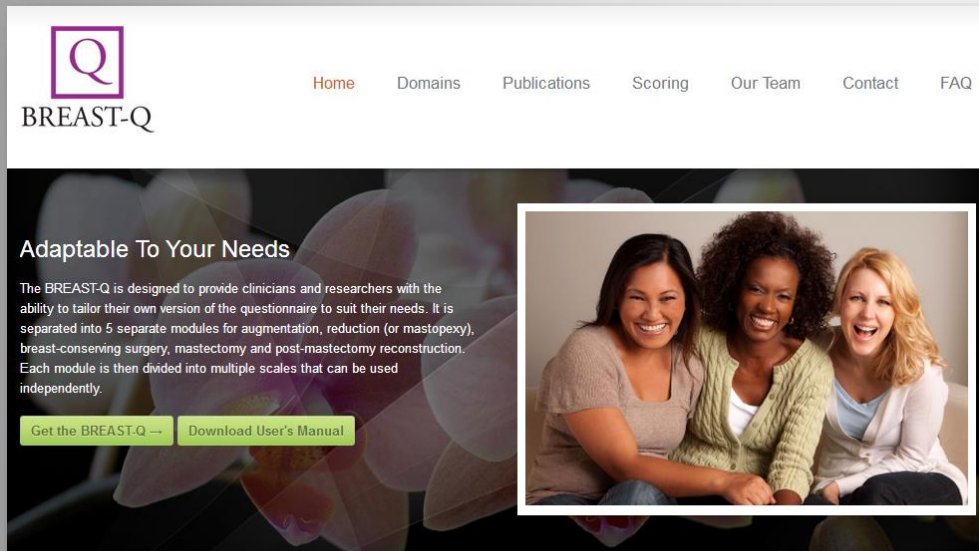
Rated Numeric Kinetic Line Scale Scores for Facial Wrinkles Secondary to Hyperkinetic Function

Score	Description
0	No wrinkles
1	Wrinkles not present at rest, fine lines with facial expression
2	Wrinkles not present at rest, deep lines with facial expression
3	Fine wrinkles present at rest, deeper with facial expression
4	Deep wrinkles at rest, deep furrows with facial expression

AFPS 2004

Patient Reported Outcomes Tools

BREAST-Q and FACE-Q



Q
BREAST-Q

[Home](#) [Domains](#) [Publications](#) [Scoring](#) [Our Team](#) [Contact](#) [FAQ](#)

Adaptable To Your Needs

The BREAST-Q is designed to provide clinicians and researchers with the ability to tailor their own version of the questionnaire to suit their needs. It is separated into 5 separate modules for augmentation, reduction (or mastopexy), breast-conserving surgery, mastectomy and post-mastectomy reconstruction. Each module is then divided into multiple scales that can be used independently.

[Get the BREAST-Q](#) [Download User's Manual](#)



Proven Performance

Used world-wide in clinical trials with thousands of patients and translated into 13 different languages, it is uniquely sensitive to subtle differences in patient outcomes and highly responsive to clinical change in prospective trials.



Reliable Metrics

Developed using state of the art psychometric methods with input from over 2000 patients in Canada and the US, the BREAST-Q has been validated in over 15,000 patients and proven to be highly reliable, valid and responsive.



Customizable

A unique modular design and independently structured scales reduces the burden on patients to only answer questions that are relevant to the outcome of interest. This translates into higher patient response rates. Most scales can be completed by patients in just a few minutes.

Measuring Quality of Life in Cosmetic and Reconstructive Breast Surgery: A Systematic Review of Patient-Reported Outcomes Instruments

Andrea L. Pusic, M.D., M.H.S.
Constance M. Chen, M.D., M.P.H.
Stefan Cano, Ph.D.
Anne Klassen, Ph.D.
Colleen McCarthy, M.D.
E. Dale Collins, M.D.
Peter G. Cordeiro, M.D.

New York, N.Y.; London, United Kingdom; Vancouver, British Columbia, Canada; and Lebanon, N.H.

Background: Patient-reported outcomes in cosmetic and reconstructive breast surgery are increasingly important for clinical research endeavors. Traditional surgical outcomes, centered on morbidity and mortality, remain important but are no longer sufficient on their own. Quality of life has become a crucial research topic augmenting traditional concerns focused on complications and survival. Given this, reliable and valid patient questionnaires are essential for aesthetic and reconstructive breast surgeons.

Methods: The authors performed a systematic literature review to identify patient-reported outcome measures developed and validated for use in cosmetic and reconstructive breast surgery patients. Qualifying instruments were assessed for adherence to international guidelines for health outcomes instrument development and validation.

Measuring Outcomes That Matter to Face-Lift Patients: Development and Validation of FACE-Q Appearance Appraisal Scales and Adverse Effects Checklist for the Lower Face and Neck

Anne F. Klassen, D.Phil.
Stefan J. Cano, Ph.D.
Amie M. Scott, M.P.H.
Andrea L. Pusic, M.D., M.H.S.

Hamilton, Ontario, Canada; Plymouth, United Kingdom; and New York, N.Y.

Background: The FACE-Q is a new patient-reported outcome instrument to evaluate a range of outcomes for patients undergoing any type of facial cosmetic operation, minimally invasive cosmetic procedure, or facial injectable. This article describes the development and validation of FACE-Q scales relevant to face-lift patients.

Methods: The FACE-Q was developed by following international guidelines for patient-reported outcome instrument development. For outcomes following a

**Is this Product or Device
Approved? Know the FDA**

501K Clearance

- FDA does not “approve” medical devices
- FDA “clears” them for sale
- FDA clearance does NOT imply level of efficacy
- A device may be cleared for a different use
 - RF fat reduction devices are cleared for tissue warming
- Starts with Premarket Notification to FDA
 - FDA determines if similar to device in 1 of 3 classes
 - Class I: Exempt due to minimal risk (tongue depressor)
 - Class II: Some risk
 - Class III: Support or sustain human life

“Off-Label” Use of FDA Cleared Device

- May use cleared device “off-label” to treat
- May NOT use for research unless IRB approved
- Is this device approved?



The screenshot shows the FDA website's navigation bar with the logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". The navigation menu includes "Home", "Food", "Drugs", "Medical Devices", "Radiation-Emitting Products", "Vaccines, Blood & Biologics", and "Animal". The main content area is titled "Premarket Approval (PMA)" and includes a breadcrumb trail: "FDA Home > Medical Devices > Databases". A text box explains that PMA is the FDA process for Class III medical devices, which are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. A link "Learn more..." is provided. At the bottom, there is a "Search Database" field and buttons for "Help" and "Download Files".

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal

Premarket Approval (PMA)

◀ FDA Home ▶ Medical Devices ▶ Databases

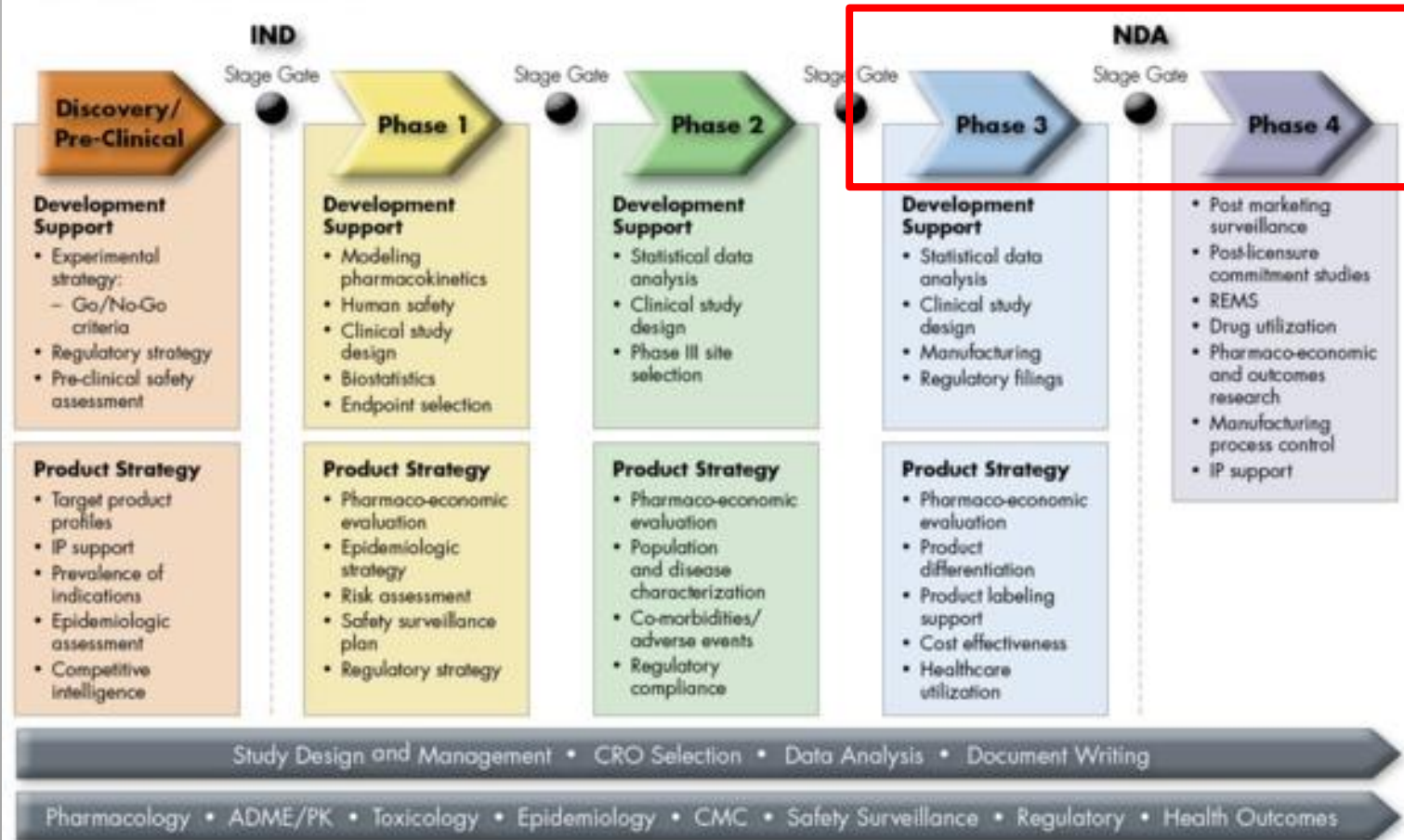
Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

[Learn more...](#)

Search Database  Help  Download Files

Pharmaceutical Process

Pharmaceutical Services



Tissue & Cell Therapies

- FDA regulates HTCP (Human cells & tissue products)
- Excludes “autologous cells recovered & implanted during the same surgical procedure”
- No premarket approval if tissue:
 - Minimally manipulated
 - Homologous use
 - Not combined with another article

Controversial:
Proceed with Caution

Working with Industry: The Pitfalls

Negative Press

- More government & public oversight

Senate Launches Investigation of Medtronic Spine Fusion Device

June 22, 2011

By JOHN FAUBER, Milwaukee Journal Sentinel/MedPage Today



- Association with “bad” product

Spine Experts Repudiate Medtronic Studies

By BARRY MEIER and DUFF WILSON

Published: June 28, 2011 |  59 Comments

The New York Times

- Ghostwriting by Industry

Report Urges More Curbs on Medical Ghostwriting

By NATASHA SINGER

Published: June 24, 2010

The New York Times

Physician Payment Sunshine Act

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Open Payments

Open Payments

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Open Payments

Creating Public Transparency of Industry-Physician Financial Relationships

The Official Website for Open Payments (Physician Payments Sunshine Act)

Open Payments creates greater transparency around the financial relationships of manufacturers, physicians, and teaching hospitals. The program requires that the following information is reported annually to CMS:

- [Applicable manufacturers](#) of covered drugs, devices, biologicals, and medical supplies to report payments or other transfers of value they make to [physicians](#) and [teaching hospitals](#) to CMS.
- Applicable manufacturers and [applicable group purchasing organizations \(GPOs\)](#) to report to CMS certain ownership or investment interests held by physicians or their immediate family members.
- Applicable GPOs to report to CMS payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year.

Intellectual Independence

- Institutional guidelines
 - Preserve independence & control
- Identify common goals with industry
 - Win-win situation
 - Funding and resources for your research
 - Favorable results with a product
 - Identify contraindications/flaws with products
- Conflict of interest
- Don't be a "Hired gun"
- Bias towards positive results
 - Study design
 - Result reporting

Intellectual Property

- Institutional guidelines
 - Protect your and institutions IP
- Document everything
 - Signed & dates notebook
 - Archive emails
 - Unopened certified letters
 - Nondisclosure agreements
 - Patent issues
- Have these discussions early in the process

Funding for your Innovation

Funding Sources: Industry

- More complex
- More restrictions
- Perception of bias
- May provide products or device
- May provide statistical & analytic support
- Need established relationship and track record



Funding Sources: Professional Organizations

- Formal grant process
- Consider grant writing workshop
- Partner with established researcher



THE AESTHETIC SURGERY EDUCATION
AND RESEARCH FOUNDATION



THE PLASTIC SURGERY
FOUNDATION ®

Funding Sources: Institutional

- Hospital grants
- Academic center grants
 - Include residents
 - Need faculty member
- Start-up and pilot-study grants
- Institution may benefit
 - More external grants
 - Public relations

Other Funding Sources

- Philanthropy organizations
- Service organizations
- Grateful individuals & patients



Presenting, Publishing and Disseminating your Innovation

Disseminating Innovation

- Public education & relations
- Paper presentations
- Trade publications
- Journal publications



Public Education & Relations

PRWeb
 Online Visibility from Local

HOME NEWS CENTER BLOG

Front Page Arts Business Education Environment Government Indus

Tuesday, April 16, 2014

New Jersey Plastic Surgeon Dr. Larry Weinstein Implements New VECTRA 3D Imaging System to Simulate Surgical Results

Dr. Larry Weinstein, a Morristown, NJ plastic surgeon, is now utilizing the VECTRA 3D Imaging System to better simulate surgical outcomes for patients seeking face, nose, body and breast enhancement through cosmetic plastic surgery.

Morristown, NJ (PRWEB) October 11, 2013

Dr. Larry Weinstein, a Morristown, NJ plastic surgeon, is now utilizing the VECTRA 3D Imaging System to better simulate surgical outcomes for patients seeking face, nose, body and breast enhancement through cosmetic plastic surgery.

Dr. Weinstein is one of just a few plastic surgeons in Northern New Jersey to implement this simulation technology. The 3D imaging allows patients to make more informed decisions about their cosmetic surgery procedure. It also allows Dr. Weinstein the ability to create a more specific surgical plan for each patient and couple advice with the surgical skills and artistic approach to plastic surgery.

The VECTRA 3D simulator was primarily designed for patients looking for a breast augmentation.

[Dr. Weinstein BREAST IMPLANTS expert](#)

HOME PAGE TODAY'S PAPER VIDEO MOST POPULAR TIMES TOPICS

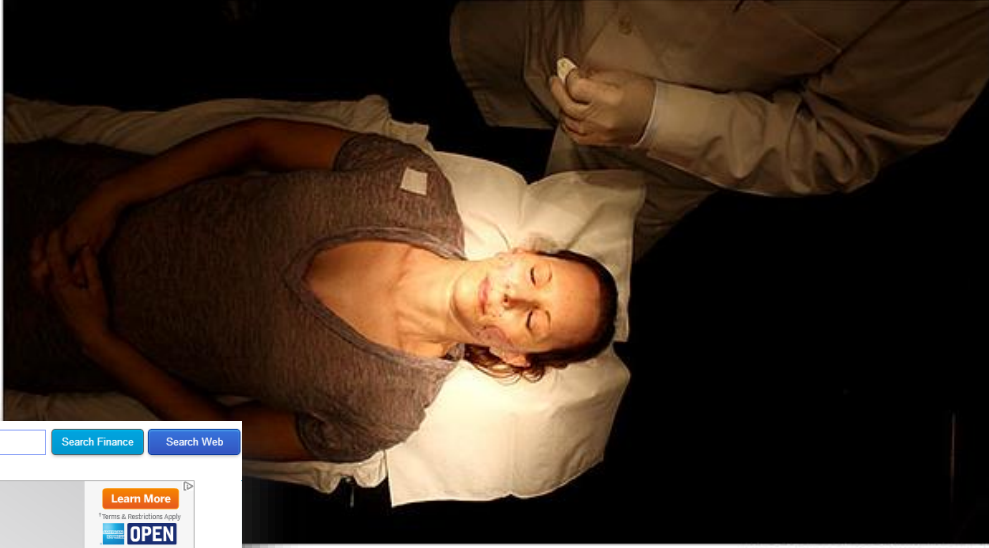
The New York Times

Fashion & Style

WORLD U.S. N.Y. / REGION BUSINESS TECHNOLOGY SCIENCE HEALTH SPORTS OPINION

SKIN DEEP

A Facial Filler Needs a Dose of Patience



Fred R. Conrad/The New York Times

...ent being treated with Sculptra in the office of Dr. Z. Paul Lorenc, a plastic surgeon in ...sunken cheeks, among other purposes.

TRIB local Glenview

HEALTH AND FITNESS [Post a story](#)

From the community

Ask the Right Questions when Considering Plastic Surgery

By North Shore University HealthSystem@NSPRZ
 Aug. 20, 2010 at 6:29 p.m.

[Tweet](#) [+1](#) [Like](#) [Email](#) [Print](#)



By Susan J. White
 NorthShore University HealthSystem

One of the most important things to consider when thinking about elective surgery for aesthetic benefit is what you hope to achieve with the procedure, according to Karol A. Gutowski, a NorthShore University HealthSystem (NorthShore) board-certified plastic surgeon with expertise in breast surgery, aesthetic and cosmetic surgery and body contouring.

Dr. Gutowski encourages potential patients to have realistic and specific goals of what they are hoping to accomplish with a procedure whether it is breast augmentation or rhinoplasty (surgery to reshape the nose).

"I want to make sure that a patient is choosing this for themselves and not doing it for someone else," Dr. Gutowski says. "If a woman comes in for a consult on breast augmentation and the husband or boyfriend is doing all the talking it's a red flag."

YAHOO! FINANCE

Tue, Apr 15, 2014, 11:34 AM EDT - U.S. Markets close in 4 hrs 26 mins

A special offer. A premium Card. **EARN 40,000** Membership Rewards® points!

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OPEN

Virginia Plastic Surgeon Uses VECTRA 3D Imaging to Simulate Patient Results

Dr. Behzad Parva Utilizes Innovative VECTRA 3D Imaging System to Help Patients Visualize Possible Post-Surgical Results for Breast, Body, and Facial Cosmetic Surgery

MARKET WIRED Parva Plastic Surgery November 20, 2013 5:07 AM

[Y](#) [+](#) [X](#) [t](#) [f](#) [TW](#) [M](#)

Paper Presentations

- Hospital Conferences
- Local & Regional Societies
 - Consider non-plastic surgery organizations
- National societies
 - More formal applications
 - Competitive
 - Long lead time
 - Industry exposure



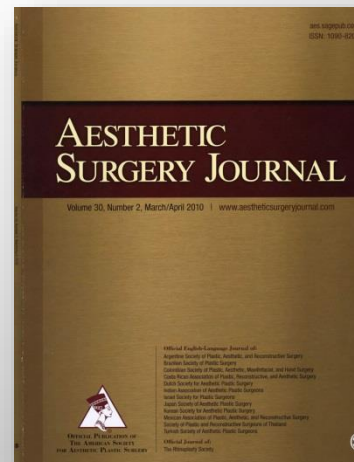
Trade Publications

- Less science, more trends and opinions
- Industry exposure
- Patient PR tool



Professional Journal Publications

- More science, less opinion
- Best industry exposure
- Need to plan before starting the project
- Time intensive if doing it alone
- Consider partnerships



The Components

- Abstract
- Introduction
- Methods
- Results
- Tables and Photos
- Discussion
- References

Authorship

- Explicit assigning responsibility & credit
 - Conception
 - Design
 - Execution
 - Analysis & interpretation
- NOT a right to inventorship or copyright
- Be able to explain & defend the study
- Define upfront with industry & other partners

Embracing Innovation: The Process of Research & Publication in Practice

Karol A Gutowski, MD, FACS

The Aesthetic Meeting 2014

BUILDING THE BRIDGE BETWEEN SCIENCE AND ART

San Francisco April 24–29 Moscone Center



Course Information & Objectives

Monday, April 28
4:30pm – 6:30pm

716 From Hot Topics to a Hot Practice – How Innovation Can Drive a Thriving Practice

2 CME credits — *Discounted pre-registration fee: \$140 On-site fee: \$190*

Joe Gryskiewicz, MD, Karol Gutowski, MD and Brian Kinney, MD

Level: Basic/Comprehensive **Organization:** Panel

Who is allowed to attend **Surgeons/Spouse/Physician's Assistants/Registered Nurses/Office Personnel/Exhibitors**

Course allowed to be recorded: **Yes**

Any additional AV requirements beyond basic set up (basic includes 1 screen, LCD projector, microphone, laser pointer): **No**

3-5 goals or objectives for the course:

- **Develop expertise in surveying the tech environment and identifying ideas for development**
- **Creating a successful business plan, dealing with investors and managing money wisely**
- **Navigating the FDA and establishing preclinical designs**
- **Evaluating scientific success and business success , what works, what doesn't**
- **Establishing relationships with companies, working as a team and maintaining independent credibility**
- **How to evaluate and compare competing products (toxins, energy devices, etc.)**
- **Developing clinical expertise with new products, best practices**
- **Differences and challenges in practice setting type (Private Practice, Academic, Group Employed)**
- **Presenting & publishing**
- **Marketing your innovative practice**
- **Assess scientific success and business success, deciphering what works and what does not**