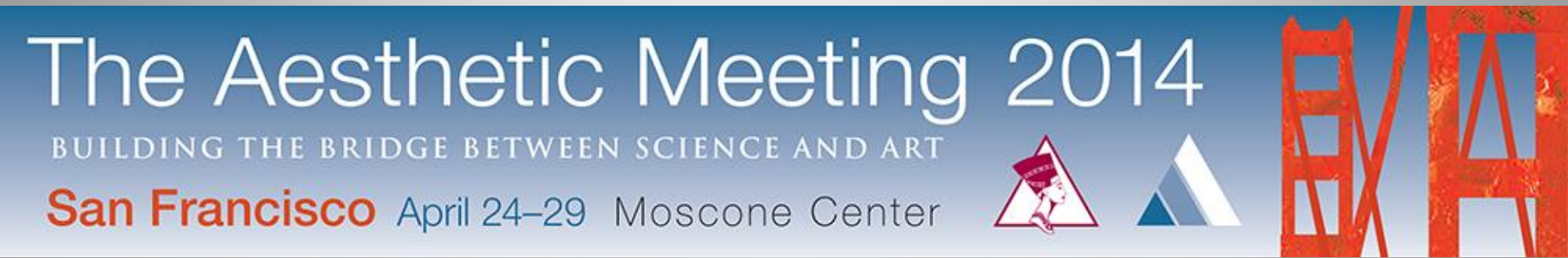
# Embracing Innovation: The Process of Research & Publication in Practice

*Karol A Gutowski, MD, FACS*



# 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

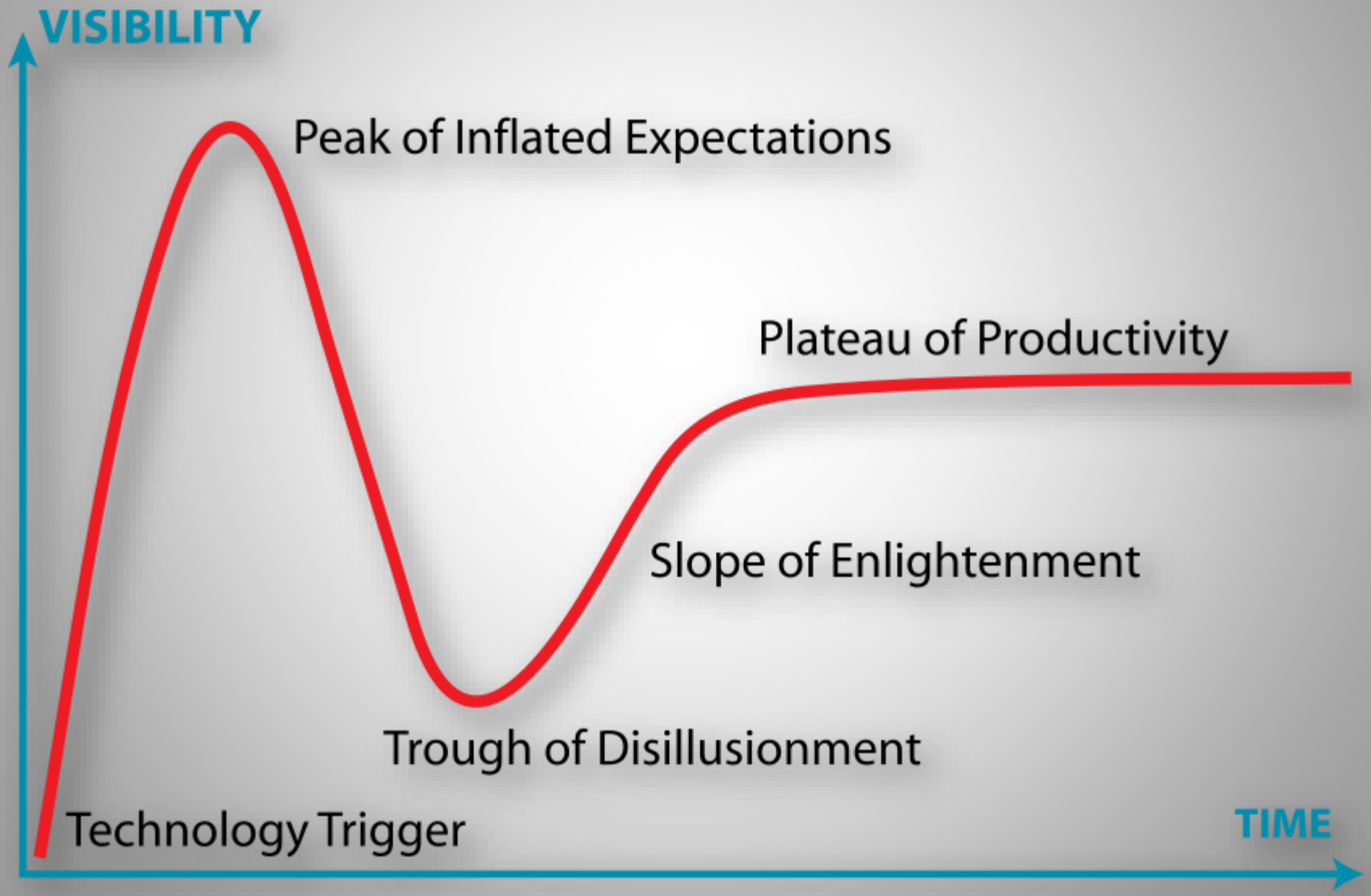
# Learning Objectives

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

# General Concepts

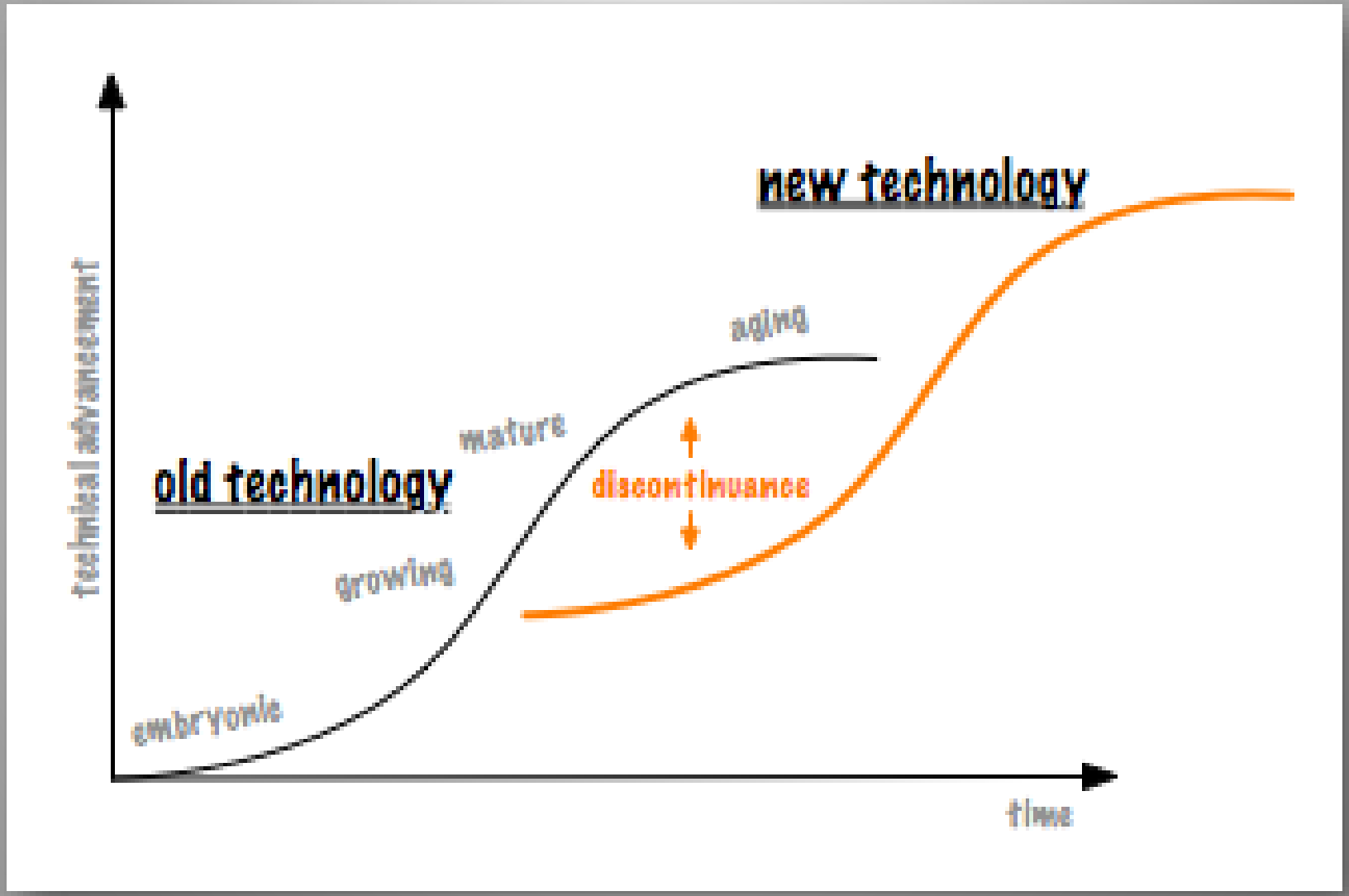
- Scientific approach to innovation
- Ask the question
- Set up the study
- Do the study
- Spread the news!
- Consult - Contribute

# The “Hype Cycle”

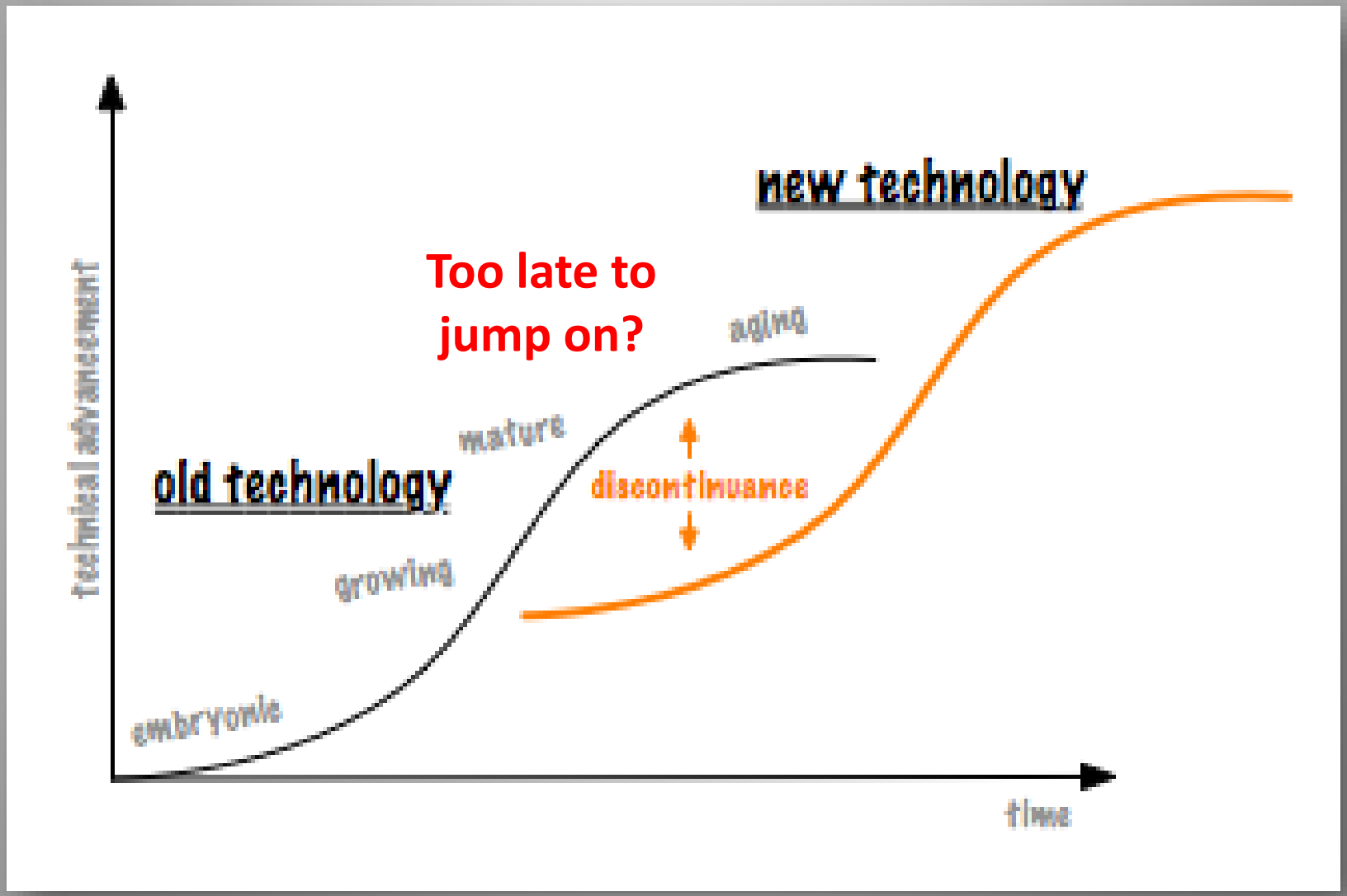


# The “Hype Cycle”

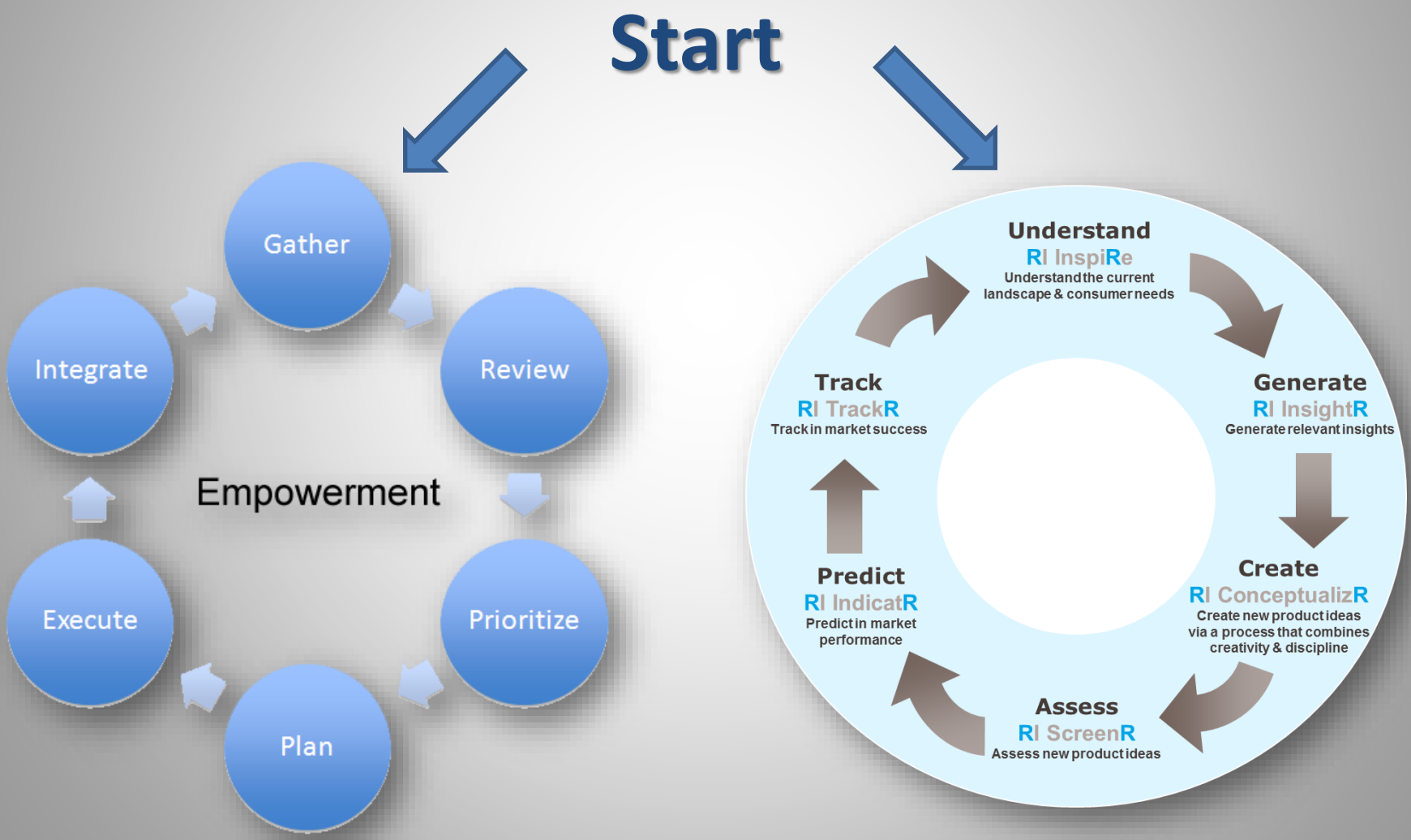
# Technology Overlap & Overtake



# Technology Overlap & Overtake



# Innovation Cycles



# 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”

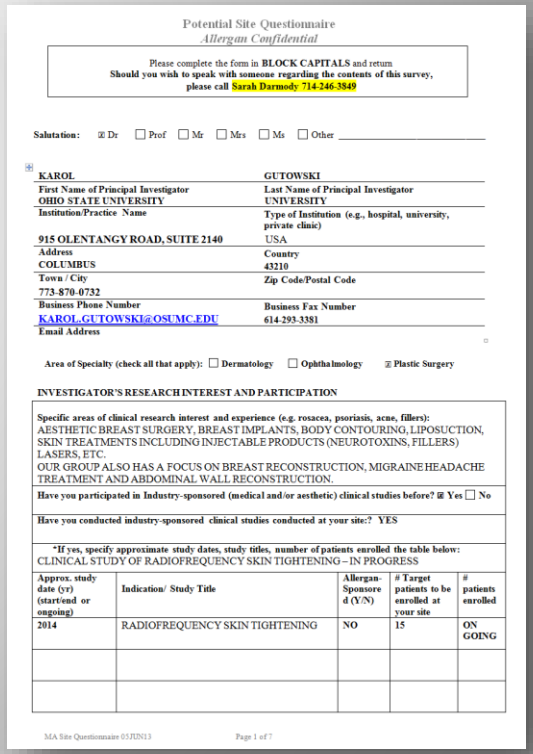
# Ways to Get Started

- 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 Darmody 714 246-3849**

**Salutation:** ☒ Dr ☐ Prof ☐ Mr ☐ Mrs ☐ Ms ☐ Other _____

| | |
|---|---|
| **KAROL** | **GUTOWSKI** |
| **First Name of Principal Investigator** | **Last Name of Principal Investigator** |
| **OHIO STATE UNIVERSITY** | **UNIVERSITY** |
| **Institution/Practice Name** | **Type of Institution (e.g., hospital, university, private clinic)** |
| **915 OLENTANGY ROAD, SUITE 2140** | USA |
| **Address** | **Country** |
| **COLUMBUS** | **43210** |
| **Town / City** | **Zip Code/Postal Code** |
| **773-870-0732** | |
| **Business Phone Number** | **Business Fax Number** |
| **KAROL.GUTOWSKI@OSUMC.EDU** | **614-293-3381** |
| **Email Address** | |

**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. rosacea, 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 05JUN13 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**

# Avoid the IRB Pitfalls

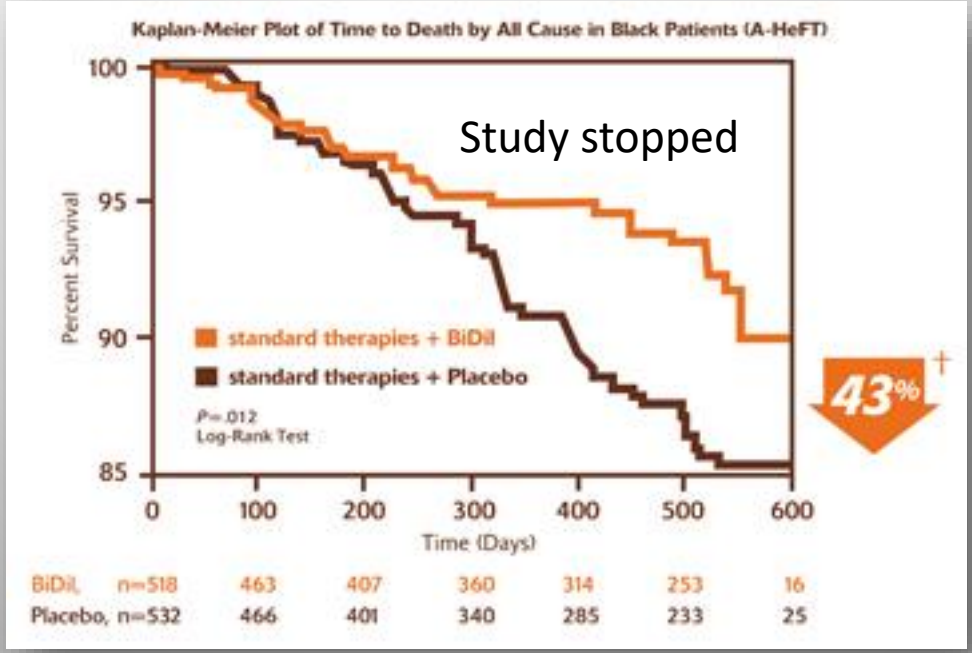
- Play by the rules
  - Ask for guidance from IRB
  - Review every submission & revision yourself
- If you don't
  - Not get published
  - Be sanctioned
  - Shut down research

# 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

# 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


CONSORT

CONSORT

TRANSPARENT REPORTING of TRIALS

# 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

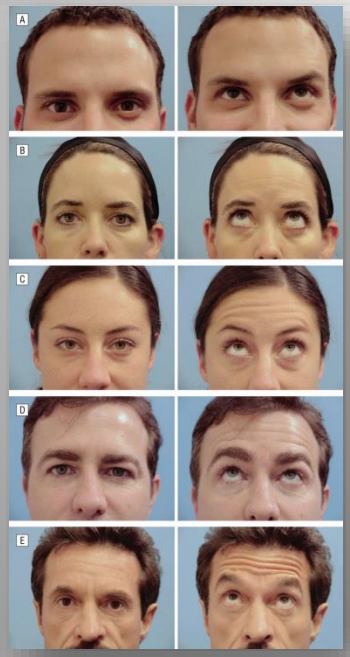
# Design the Project

- 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

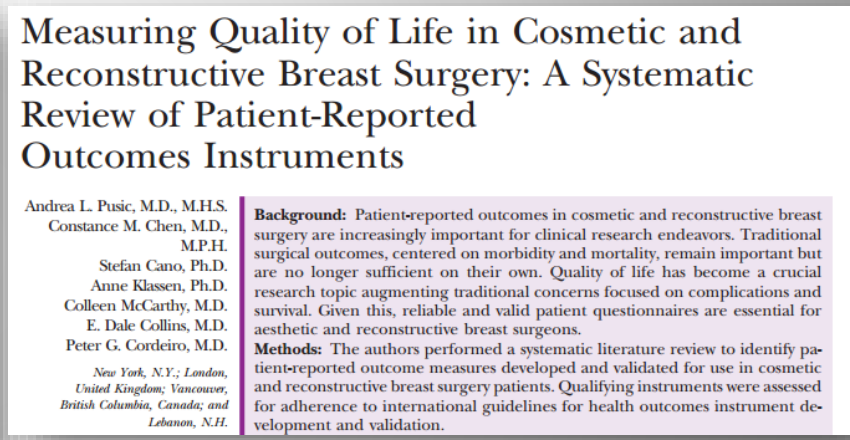
**Rated Numeric Kinetic Line Scale Scores for Facial Wrinkles Secondary to Hyperkinetic Function**

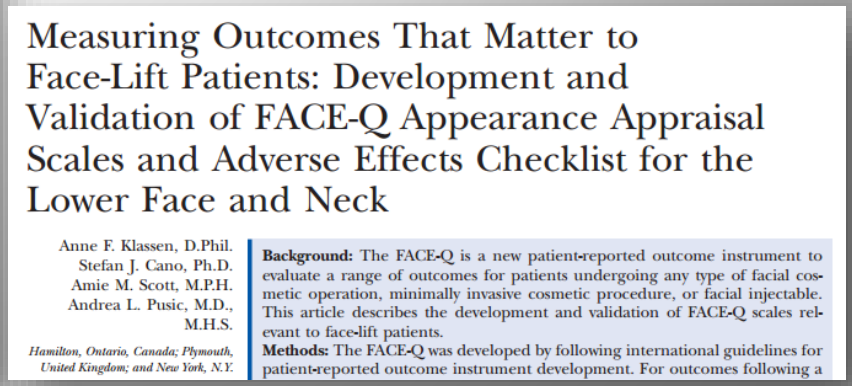
| Score | Description |
|---|---|
| 0 | No wrinkles |
| 1 | Wrinkles not present at rest, fine lines with facial expression |
| 2 | Wrinkles not present at rest, deep lines with facial expression |
| 3 | Fine wrinkles present at rest, deeper with facial expression |
| 4 | Deep wrinkles at rest, deep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

AFPS 2004

# Patient Reported Outcomes Tools

## *BREAST-Q and FACE-Q*

# Is this Product or Device Approved? Know the FDA

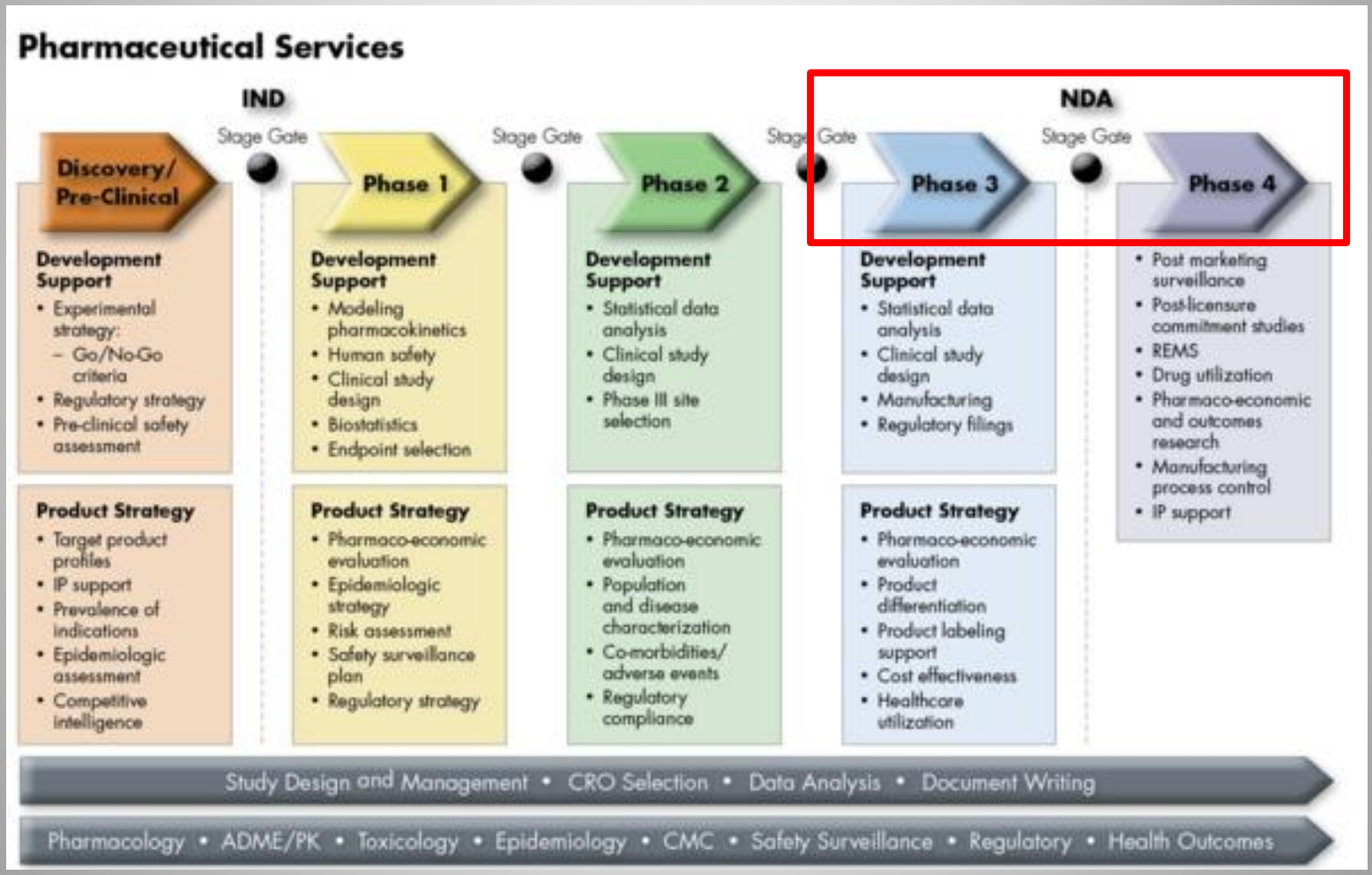
# 501K Clearance

- 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?

# Pharmaceutical Process



# Tissue & Cell Therapies

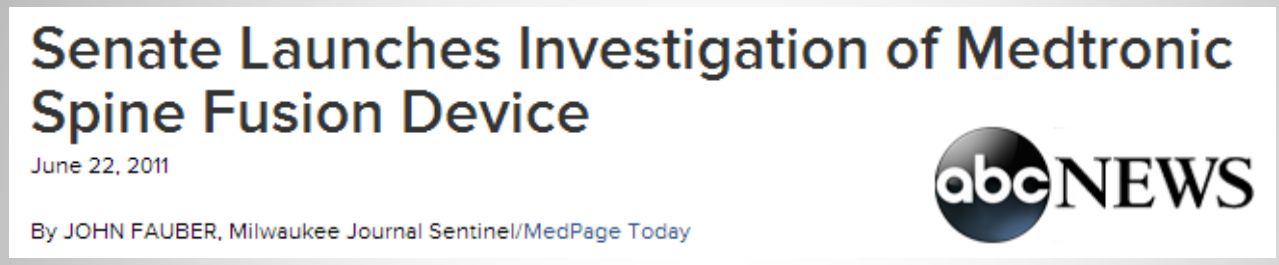
- FDA regulates HTCP (Human cells & tissue products)
- Excludes “autologous cells recovered & implanted during the same surgical procedure”
- No premarket approval if tissue:
  - Minimally manipulated
  - Homologous use
  - Not combined with another article

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

abcNEWS

- Association with “bad” product

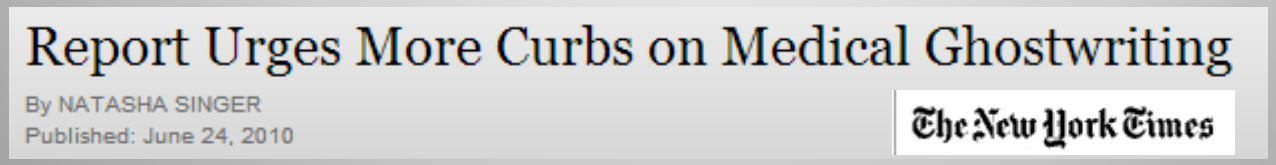

Spine Experts Repudiate Medtronic Studies

By BARRY MEIER and DUFF WILSON

Published: June 28, 2011 | 59 Comments

The New York Times

- Ghostwriting by Industry

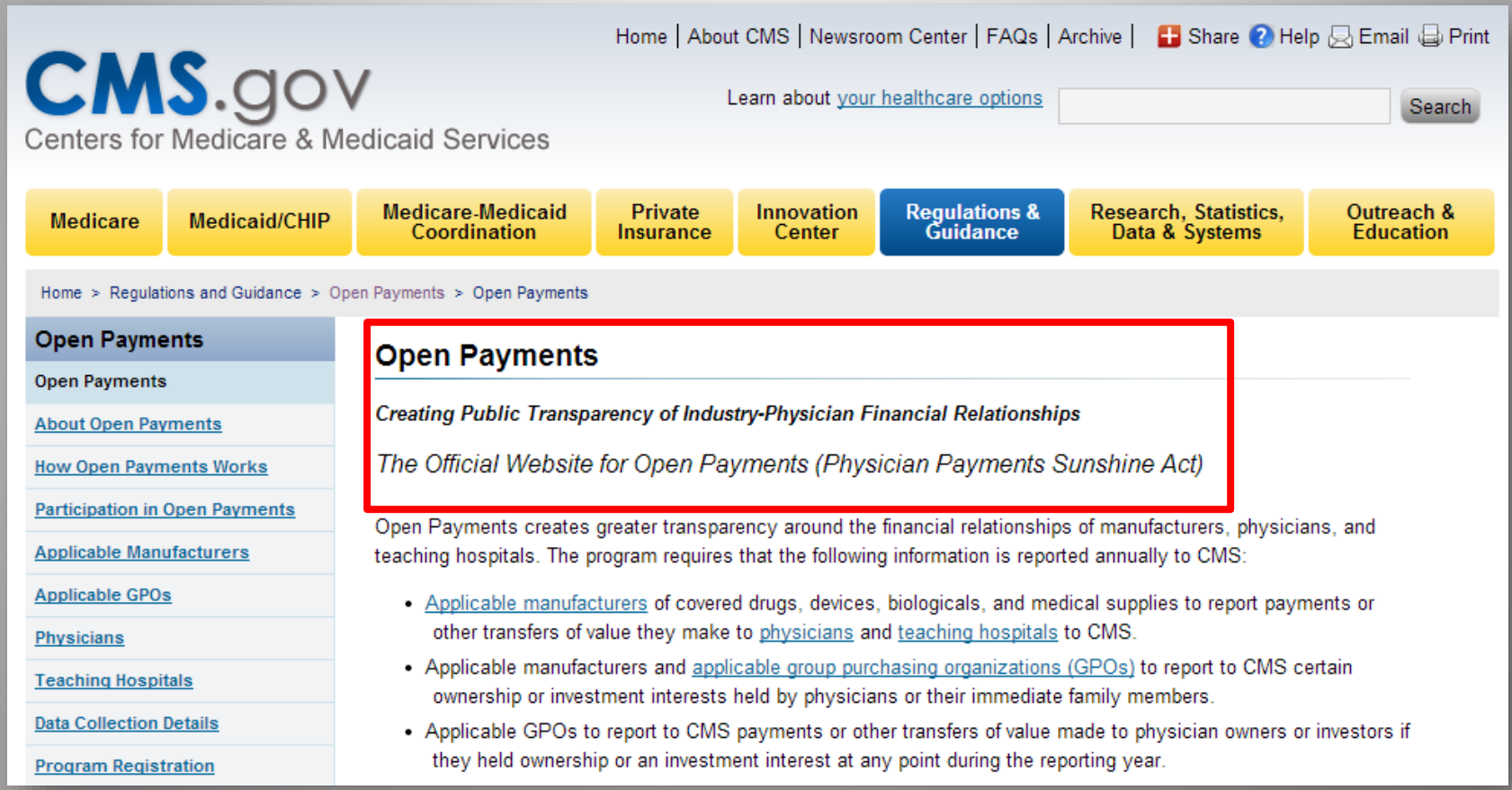

Report Urges More Curbs on Medical Ghostwriting

By NATASHA SINGER

Published: June 24, 2010

The New York Times

# Physician Payment Sunshine Act



# 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


# 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

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**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


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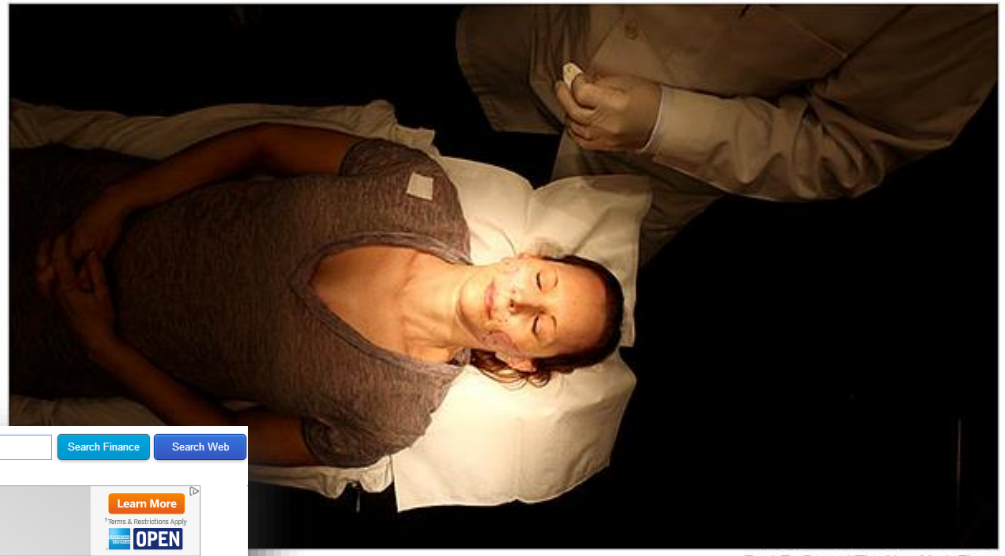
The New York Times

**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 NorthShore University HealthSystem@NSPR2
Aug. 20, 2010 at 5:29 p.m.

Tweet 3 | +1 0 | Like 0 | 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

Search Finance | Search Web

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



## 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

# Paper Presentations

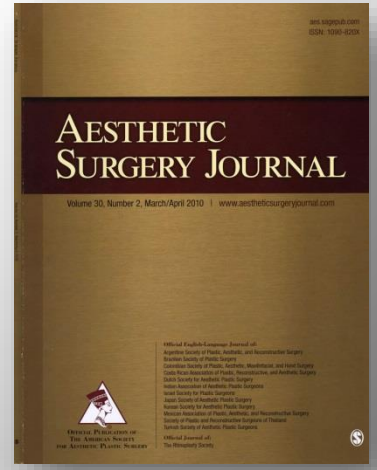
- Hospital Conferences
- Local & Regional Societies
  - Consider non-plastic surgery organizations
- National societies
  - More formal applications
  - Competitive
  - Long lead time
  - Industry exposure

# 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 staring 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**