


I-SPY 2 TRIAL


www.ispy2.org

**I-Spy 2:
How Advocates Are Involved in a
Trial with an Innovative Design**


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**How Much Do You Know About
I-SPY 2?**

1. Never heard of it before seeing the agenda
2. Have heard of it, but don't know anything about it
3. Know a very little about it
4. Know quite a bit about it
5. Have heard way too much about it



Topics



- **What is I-SPY 2 and how it is innovative?**
- How advocates have been involved?
- What are some key learnings?
- Next steps

I-SPY 2 Clinical Trial Background

- PI: Laura Esserman (Breast Surgeon at UCSF) & Don Berry (Biostatistician at MD Anderson)
- Early discussions beginning in 2005
- Opened in March 2010 at UCSF/Currently open in 18 sites
- Plans to treat 800 patients; ~500 through October, 2013
- Includes many unusual partnerships



I-SPY 2 Innovation: Trial Design

- Neo-adjuvant (prior to surgery) chemotherapy
- Biomarker driven trial design
- Simultaneously validating biomarkers and assessing investigational agents
- Adaptive allocation trial design
- ~ 20 % of patients in control group (standard of care)
- Investigational agents being tested in potentially curable breast cancer patients (i.e., stage 2 and 3 disease)
- Two-step consenting



I-SPY 2 Innovation: Business Model

- Multiple investigational agents from multiple companies in the same trial
- Multiple funding sources
- Early involvement of FDA and NCI
- Instigated regulatory change
- Open access to data
- Lots of "lead roles" for investigators from multiple institutions
- Extensive advocate involvement



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Four Types of Advocate Involvement

1. Advocates involved in sub-groups (~35)
2. Advocate specific projects (~40)
3. Patient advocacy at trial sites (initially about 20; currently none)
4. Informed advocacy (>175)

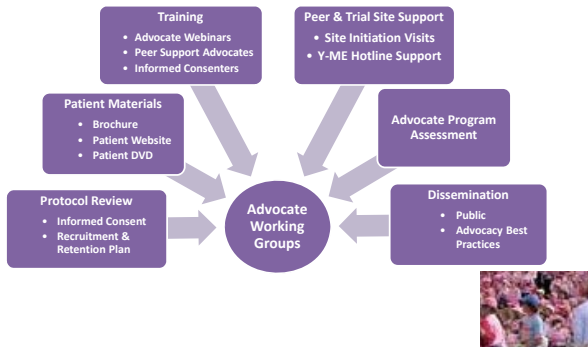


I-SPY 2 Groups

- Internal Working Groups
- External Advisory Groups
 - DSMB
 - External Drug Selection Committee
- Ad Hoc Groups
 - Piggy back studies
 - Returning individual results
 - Neoadjuvant “debate” in JCO



Advocate Specific Projects



Patient Advocacy at Trial Sites

- Some advocates participated in Site Initiation Visits
- Hoped to engage advocates with local investigators and enhances communication with local advocacy groups, press, etc.
- Y-ME peer support project



Informed Advocacy

- Advocate email updates; Investigator Newletters
- Website with I-SPY2 specific and generic research advocacy information
www.gemini-grp.com/ISPYHome.pdf
- Advocate webinar education series
- Presentations at key scientific and advocacy meetings; annual SABCS meeting



Example Changes Suggested by Advocates

- Adoption of two stage consenting process (screening and treatment)
- Decision to inform patients of their treatment during the consenting process (i.e., non-blinded study)
- Decision to inform patients when drugs they are taking are dropped and allowing them to choose whether or not to complete their treatment with such drugs



Example Changes Suggested by Advocates (continued)

- Emphasis of patient-relevant criteria into the drug selection process
- Inclusion of data collection about reasons patients decline to participate in the trial
- Availability of patient travel reimbursement for research visits
- Use of a peer support hotline for patients considering and on trial



Examples of Impacts Beyond I-SPY

- Other adaptive similar trials
- FDA guidance on using pCR for accelerated approval in neoadjuvant treatment of early stage breast cancer
- CTTI Central IRB project
- More educated advocates and investigator appreciation of advocates
- ...



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Lessons Learned: Adaptive Trials

- Adaptive trials can be a vehicle to more rapid, cost-effective progress
- Adaptive designs are increasingly being accepted by companies, researchers and FDA
- Use of allocation adaptive trials takes:
 - Careful planning
 - The right application



Lessons Learned: Innovation

- Innovation is hard, but important
- Innovation requires persistent, visionary, charismatic leadership and unique partnerships
- Many individuals have lots to offer and a keen interest in being part of change



Lessons Learned: Involving Advocates

- Different advocates have differing levels of interest and expertise
- Different investigators have differing levels of interest and ability to engage advocates
- Considerable effort is required to organize, educate and optimize advocate involvement
- There are lots of opportunities for learning and pushing the envelope



Lessons Learned: Involving Advocates (continued)

- We need to:
 - Experiment and tolerate failure
 - Assess and improve practices
 - Share best practices



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Where Should JP Spend Additional Time/Energy?

1. Write more advocate-specific updates
2. Schedule more advocate webinars
3. Initiate more advocate led projects
4. Update advocate-specific website
5. Focus on planning I-SPY 3



Which Advocate Led Projects are Likely to be Most Impactful

1. Returning summary results
2. Returning individual results
3. Enhancing patient interface
4. Recruiting more diverse patients/sites
5. Involving advocates at local sites



Would You be Interested in Being Involved?

1. Leading an advocate project
2. Being involved in an advocate-led project
3. Getting on the advocate mailing list
4. Leveraging I-SPY experience into your own work

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