

New Ways of Engaging Research Participants & Novel Consent Models

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National Institutes of Health Precision Medicine Initiative

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***We have an
opportunity...***

Engaging Research Participants

- Partners
 - Not patients, co-investigators
 - Not ‘at the table’, planning the meal
- Frictionless
 - In communities, with community leaders
 - Where we live and play, in pathway
- Relevance/Value/Benefit
 - Our questions, meet needs
 - Results are visible and tangible
 - Solve my problems (kid’s immunizations to school, mother’s health record to Minute Clinic)
- Beyond advocates and advocacy to affinity

Culture Challenge

- Empowering, non-paternal (maternal)-istic
- Grow up investigators (participants, clinicians), not helicopter science, get out of medical mindset
- Set the passion of people on fire, it will fuel the PMI
- Ask a lot, give a lot
- Provide proximate on-ramps
- Trust environment
- Face our fears (we are afraid of people participating, we are afraid, we hate risks, not BUT **AND**)
- Participants step up and stop apologizing
- Transparency – go, go, go – we can lead, follow, dance, run... forgive.

Relational
(not transactional)

Watch our language

“When we LET patients...

- Engage
- Participate
- Partner

If this is real, then we are not LETTING,
we ARE partners, without permission...

Consent

Not consent, engagement

Engagement, including Fair Information
Practices

PROCESS

The Problem

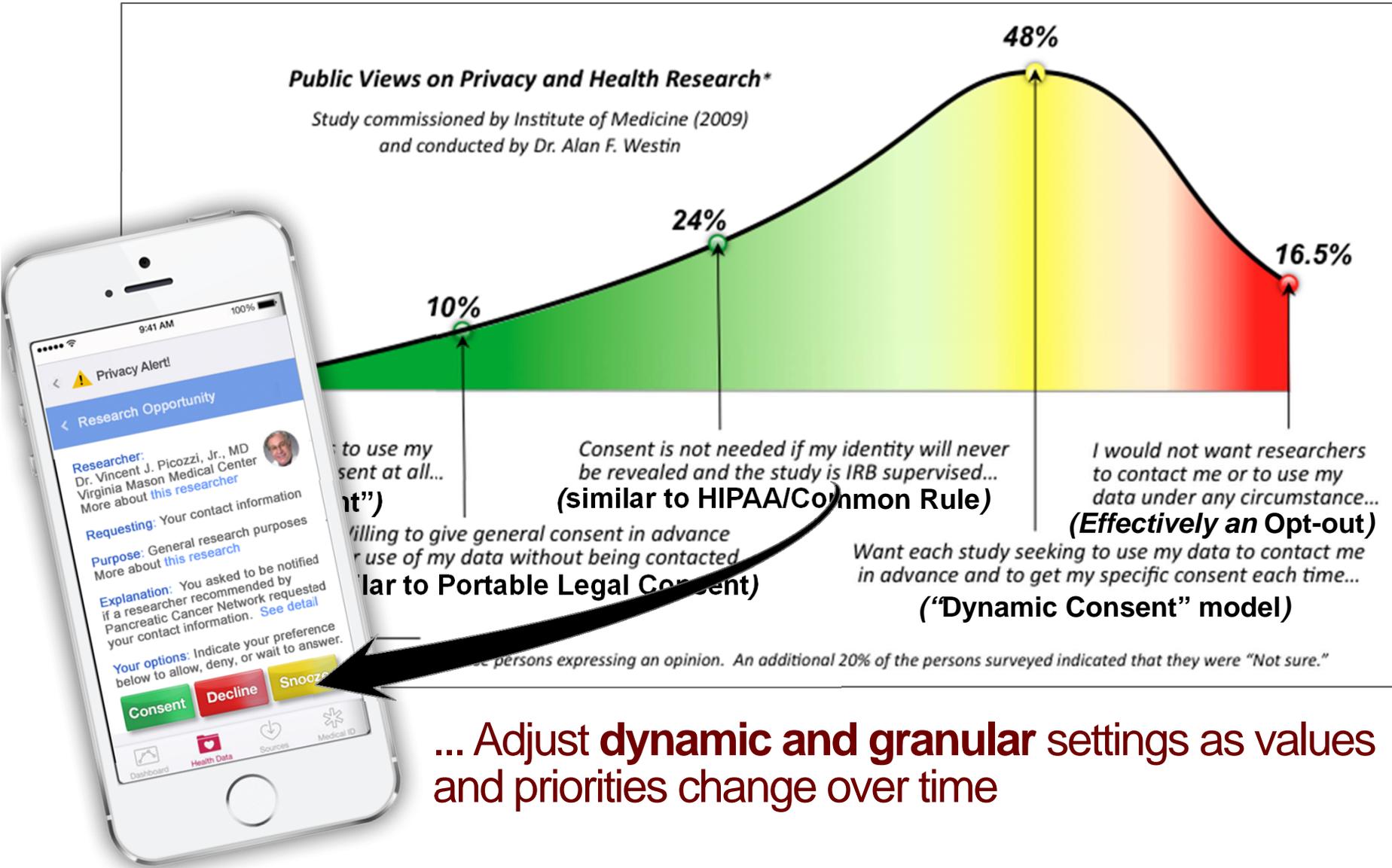
- Broad consent artificially **limits the willingness of many individuals** to participate more actively in research of their choosing, and to express preferences about future data sharing and returning results;
- ‘One-time consent’ **limits access for future uses** of the information that cannot possibly be foreseen (or risks assessed) at the time such waiver of consent is sought;
- Data silos **limit the ability of researchers to find significant correlations**, epigenetic effects, and identify trends across diverse populations, diseases, pathways, and/or systems; or through analysis of longitudinal data;
- The **policy issue extends well beyond federal privacy laws**, as State (and in some instances even local) law differences between jurisdictions make it impossible to locate a single source for knowing the rules associated with releasing information such that the safest thing is to not share except in the most aggregated -- and therefor least useful -- form.

Health Data Exploration Project: Personal Data for the Public Good

Robert Wood Johnson Foundation 2014

“...individuals’ willingness to share is dependent on what data is shared, how the data will be used, who will have access to the data and when, what regulations and legal protections are in place, and the level of compensation or benefit (both personal and public).”

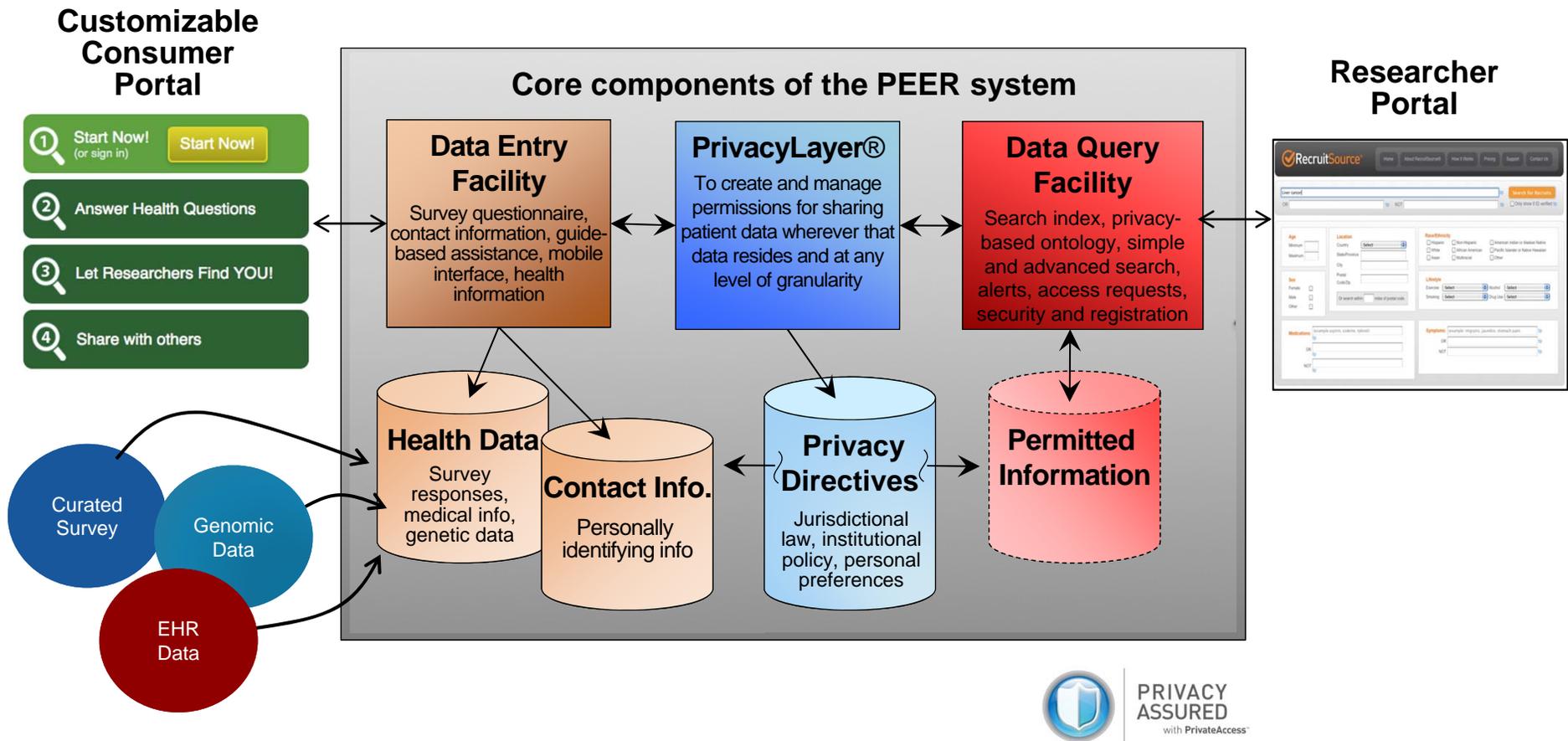
Platform for Engaging Everyone Responsibly (PEER)



... Adjust **dynamic and granular** settings as values and priorities change over time

PEER Logical Components and External Interfaces

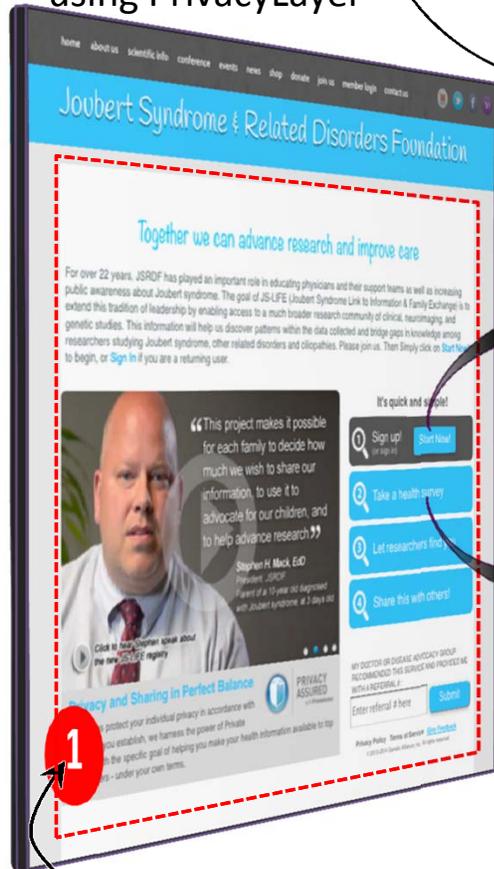
PEER provides tools to customize the consumer portal and the researcher portal, including selection of guides and curation of questions, along with administrative tools to help host organizations manage their PEER site



PEER: Creating an environment of trust

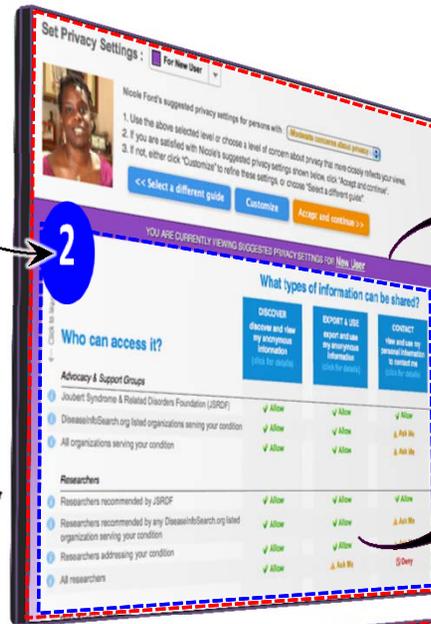
Privacy Set Up:

Individual registers and sets privacy preferences using PrivacyLayer®



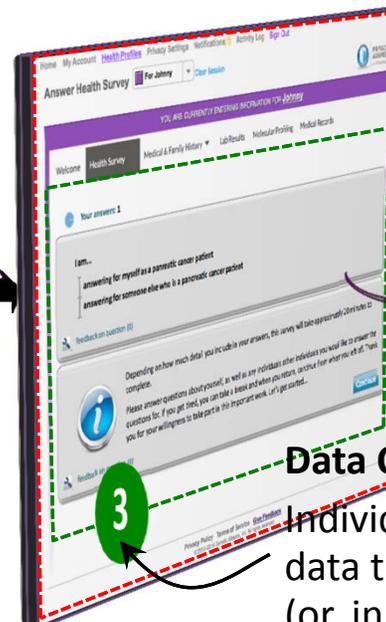
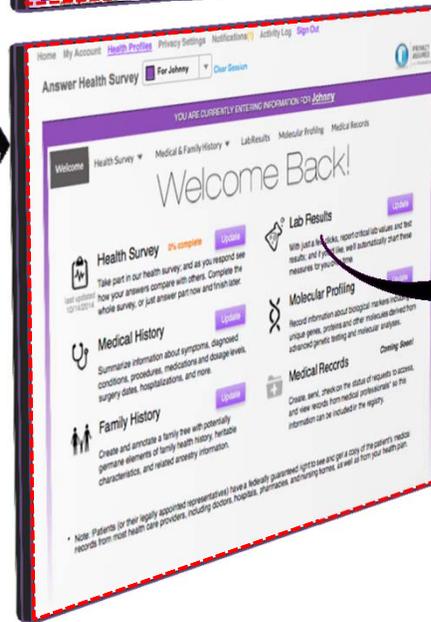
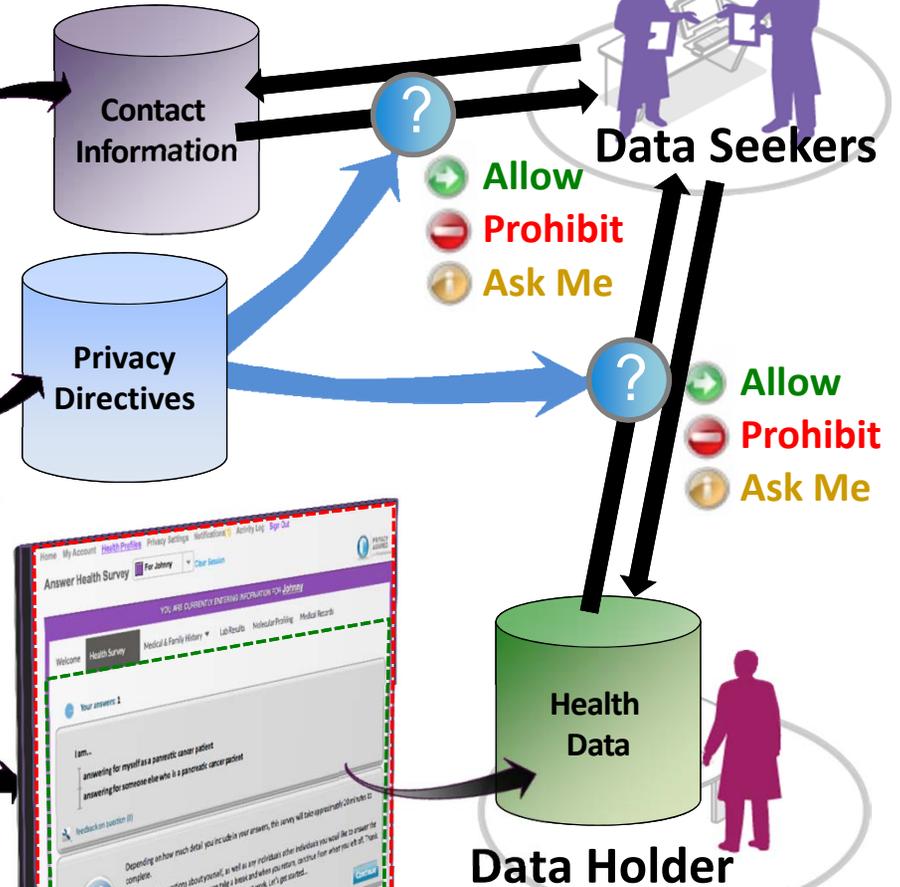
Set-up:

Trusted organization simply embeds a PEER entry point into its website



Data Access:

Data Seekers access health data and contact information, as authorized



Data Capture (or Order):

Individual provides health data through survey questions (or, in future, from their EHR)

To the consumer, privacy is a surrogate issue for *TRUST*

Nearly 90% of all respondents reported a high degree of trust in how their personal information in PEER would be handled



Asked how confident they were their wishes for how their personal health and contact information would be used as they expressed, participants said they felt...

	Response Percent
Complete or general sense of trust	89.4%*
Only some trust	4.4%
Uncertain whether wishes will be followed	4.4%
Concerned wishes will not be followed	1.8%

* Average of users of several PEER portals.

Participants establish their own sharing preferences based on simple “stop-light” metaphor – **Allow**, **Deny** or **Ask Me**

YOU ARE CURRENTLY VIEWING SUGGESTED PRIVACY SETTINGS FOR New User

What types of information can be shared?

	DISCOVER discover and view my anonymous information (click for details)	EXPORT & USE export and use my anonymous information (click for details)	CONTACT view and use my personal information to contact me (click for details)
Who can access it?			
Advocacy & Support Groups			
Joubert Syndrome & Related Disorders Foundation (JSRDF)	✔ Allow	✔ Allow	✔ Allow
DiseaseInfoSearch.org listed organizations serving your condition	✔ Allow	✔ Allow	⚠ Ask Me
All organizations serving your condition	✔ Allow	✔ Allow	⚠ Ask Me
Researchers			
Researchers recommended by JSRDF	✔ Allow	✔ Allow	✔ Allow
Researchers recommended by any DiseaseInfoSearch.org listed organization serving your condition	✔ Allow	✔ Allow	⚠ Ask Me
Researchers addressing your condition	✔ Allow	✔ Allow	⚠ Ask Me
All researchers	✔ Allow	⚠ Ask Me	🚫 Deny
Data Analysis Platforms			
"Show related content" feature	N/A	✔ Allow	N/A
"Compare with others" feature	N/A	✔ Allow	N/A
Genetic Alliance Translational Research Network	✔ Allow	✔ Allow	N/A
PCORnet: Patient-Centered Outcomes Research Network	✔ Allow	⚠ Ask Me	⚠ Ask Me
Newly-Released Data Analysis Platforms	⚠ Ask Me	⚠ Ask Me	N/A

[<< Select a different guide](#)
[Customize](#)
[Accept and continue >>](#)

“Guides” Help Participants Decide Upon Permissions

User can set for each member of her family, or use an existing group of settings as the basis for others

Home My Account Health Profiles **Privacy Settings** Notifications(1) Activity Log Sign Out

Select a guide : For New User

Set your privacy preferences manually, or select a guide who has studied the options and made suggestions for persons with high, medium and low concerns about privacy. Select a guide who you know, or whose experience or perspectives you value.

Sarah Haislip
South Regional Co-Leader for the Daughters of Pulmonary Fibrosis
I'm a South Regional Co-leader for the Daughters of Pulmonary Fibrosis, a sisterhood for the Coalition for Pulmonary Fibrosis (CPF). I lost my dad back in April of 2012, he was only 62 years old. Fighting for this cause has become a passion of mine.
... More >>
Select Sarah as your guide

Maryluz Fuentes, M.D. M.S.P.H.
Attending Family Practice Physician
Montgomery Primary Medicine Associates
Dr. Fuentes is a physician Board certified in Family Practice medicine currently in private practice. She was diagnosed with Idiopathic Pulmonary Fibrosis at a relatively young age of 47. Her training in primary care allows her to be part of the team that c
... More >>
Select Maryluz as your guide

George Lapidis
74 year old Sports Journalist Living with IPF
I am 74-year old mostly retired sports journalist although I still host a sports talk show on radio in Memphis three days a week for one hour a show. My show is in its 43rd year, making it -- by far -- the longest running sports talk show in the co
... More >>
Select George as your guide

Create Preferences Manually
If you are comfortable using this tool, you can set your preferences manually.
Set preferences manually

What's this?

PRIVACY ASSURED
Private Access lets you control who can see your information, and for what purpose. This service will check your Private Access settings before sharing any of your information.

Privacy Policy Terms
© 2013-2014 Genentech

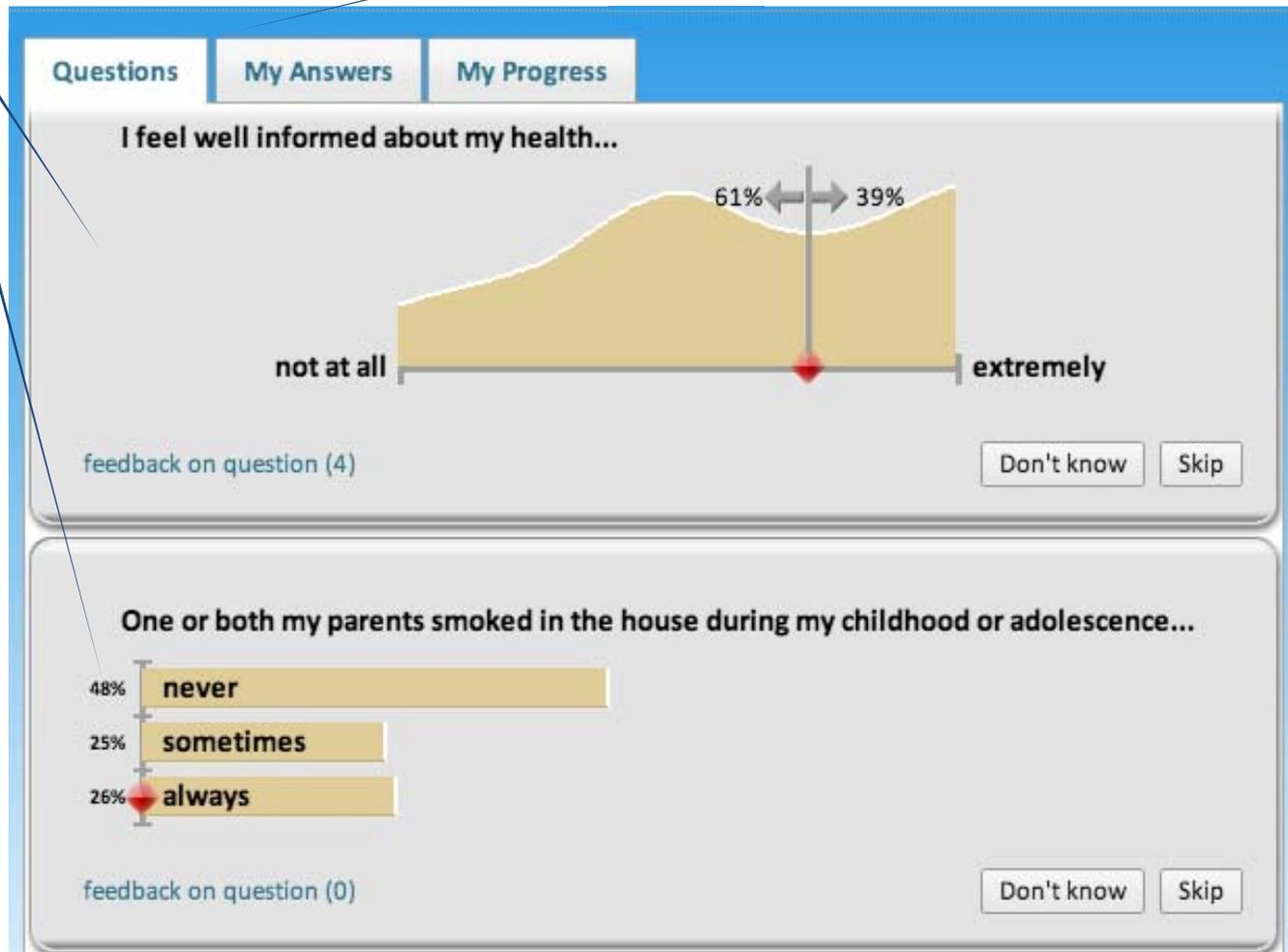
Audit log for all activity is available for review at any time

Dynamic consents may be set from a computer or a smartphone

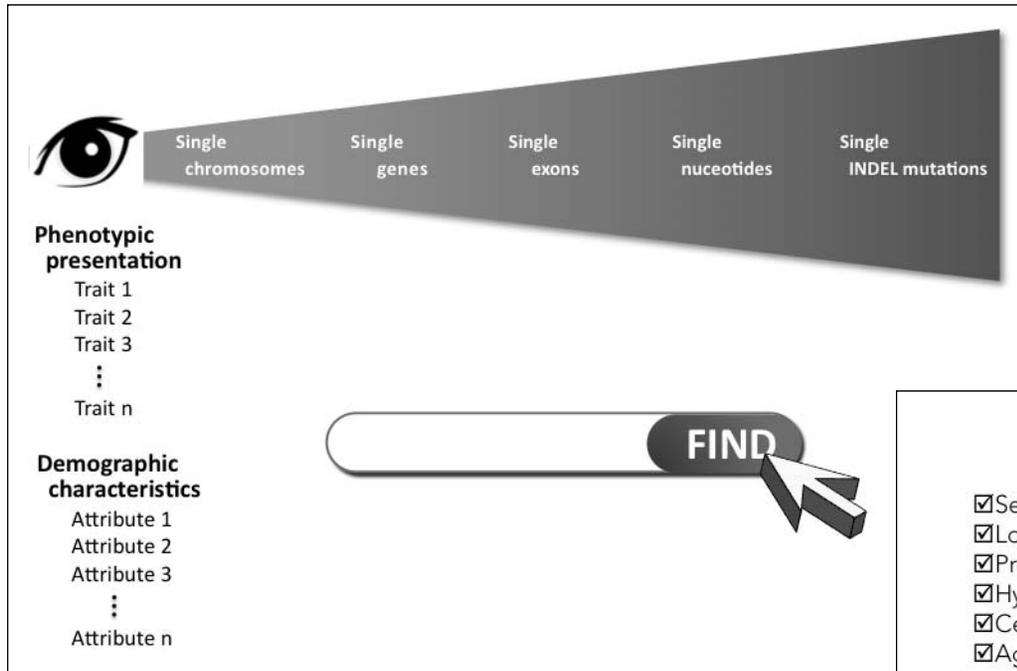
“Gamified” Interface for Questions and Answers

Questions appear in a dynamic user interface, and provide immediate feedback on how others responded to the same question...

Participants can review their prior answers, make updates and/or remove the data at any time.



Matchmaking on Genotype and Phenotype



You (your child) match with:

- Seizures, grand mal, age 5 onset
- Low tone
- Progressive cognitive disability
- Hydrocephalus
- Cerebral palsy
- Aggressive behavior

Filters:

- Age 10 to 20
- United States

Found: 24 individuals

17 have enabled sharing (ALLOW), 7 have indicated ASK ME

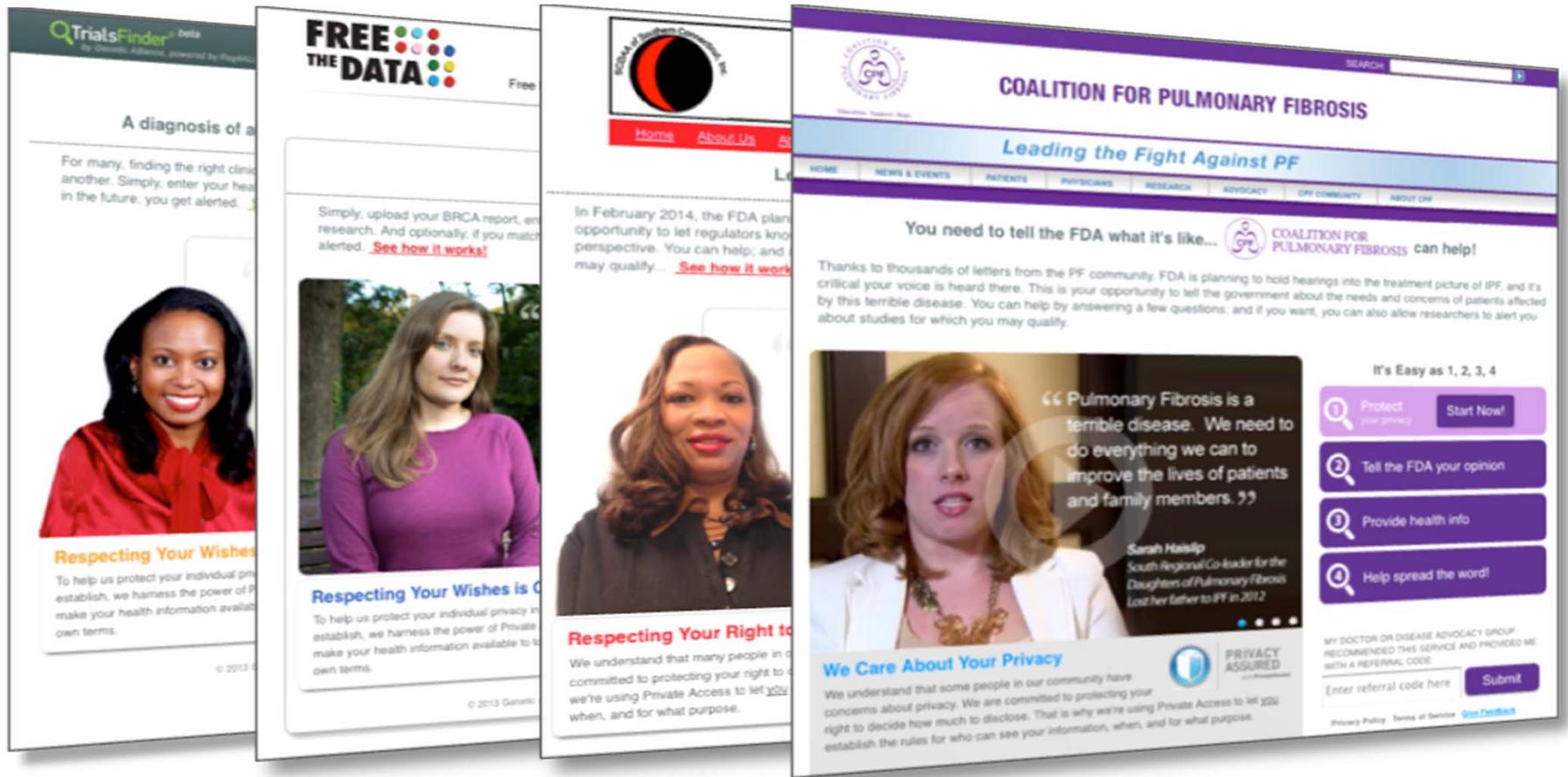
4 with exomes, 1 with genome, 15 extensive panels, 4 no testing



Adapting PEER's gamified survey to an app form



PEER is Completely Customizable



Each community brands the portal

Robert Wood Johnson Foundation Grant: White Label

Select and edit each element in the PEER portal to appear in the theme of its current website

...and view a live preview of the page as it is modified

Curate inquiries (content, sequence, dependencies, etc) from a starting point of over 22,000 questions

Also create custom badges to display on other websites

Create referral codes to use on any printed communications like letters and posters

...and view statistics for how all of these assets perform and why

The screenshot shows the 'PEER Partner Admin' interface for 'Rally4Liver'. At the top, there are navigation links for 'my account' and 'sign out'. Below this is a menu with buttons for 'Create Widget', 'Create Badges', 'Referral Codes', 'View Stats', and 'View Data'. A progress bar indicates the current step: 'STEP 3: Select Questions >>'. The main configuration area includes a 'Reset Default Colors' button, a 'Stretch to browser' checkbox, and input fields for 'Border: 1', 'Shadow: 0', and 'Corner radius: 15 pixels'. There are three main sections: 'Headline Logo (or no)' with an 'Include 255x55 JPG logo' checkbox; 'Select Featured Content' with a dropdown menu showing 'Show Host', 'Show Video', and 'Show Custom 585x353 Image'; and 'Select button functions' with a list of steps: 'Step 1: Register (or sign in)', 'Step 2: Take Survey', 'Step 3: Final Message', and 'Step 4: None'. At the bottom, there is a 'Live Preview' dropdown and a color palette with options for Theme 1, 2, and 3 colors, Link Color, Link Rollover, Link Clicked, Button Color, Button Gradient, and Background.

Code is simply placed into page source and it begins working instantly

...and data to which the group has rights can be located and downloaded in CSV format for analysis

PEER Deployed

- **PCORnet PPRN**
 - 11 Disease Advocacy Organizations
- **Robert Wood Johnson Foundation Project**
 - 30 Communities/collectives (employers, churches, gyms)
- **Campaigns**
 - Free the Data: <https://www.free-the-data.org>
 - Patient Focused Drug Development (Sickle cell, IBD, IPF)
 - Patient Preference Study (CDHR – Obesity)
- **Advocacy Initiated**
 - United Mitochondrial Disease Foundation
 - Pancreatic Cancer Action Network
 - ...
- **General Public**
 - Registries for All: <https://www.reg4all.org>
 - TrialsFinder: <https://www.trialsfinder.org>

TRUST

It's about trust

(more so than privacy)

But privacy is a **surrogate marker for trust** ...it reflects a level of **care** and **respect** that underpin trust ...and when these are not present, **people feel it** ...which undermines trust

Place the person
(and their
interests)
in the center
of everything

If we honor this
guiding principle all the rest
must follow, can follow, and **will follow**