Drug Development: Issues to Highlight

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Acceleration is not the goal

Must optimize the data collection and get the right data at right time (Schilsky)

Risks of going too fast(Harvey):

- right dose not found
- formulation wrong
- hard to recruit post market

Pressure for Speed and Access (Joffe)

In spite of all this, we need to keep science at the forefront.

We need the information so drugs can be used WELL in the Real World.

In balancing autonomy v. beneficence , I’d l place drug development on the beneficence end.

Consent Issues to think about

RWD includes Health Apps

Medwatch

A good attempt to capture Patient reported AEs

- **infrequently used and not widely known**

Abelson MB; Lafond A;Making the Most Of FDA's MedWatc; **Review of Opthamalogy** Jan 19, 2011 *https://www.reviewofophthalmology.com/article/making-the-most-of-fdas-medwatch*

Better ways could be developed to get Patient Reported AEs

Core elements of any responsive health system.

- Patient-centeredness
- Patient safety

Patients best placed to report what they experience

- HCP can “contextualize that experience in terms of the disease”

Banerjee AK et al Patient-Reported Outcome Measures in Safety Event Reporting: PROSPER Consortium Guidance. ***Drug Safety*** (2013) 36:1129-1149

Health apps need a privacy warning to alert patients

2014 Study of Android Apps for Diabetes

211 apps found

1. (81%) did not have privacy policies.

2. Those with privacy policies often did not protect privacy

    -80.5% collected user data

    - 49% shared data

3. Only 4 policies would ask users for permission to share

Blenner SR et al. Privacy Policies of Android Diabetes Apps and Sharing of Health Information: JAMA (2016)315:10

In the transmission analysis, sensitive health information (eg, insulin and blood glucose levels)was routinely collected and **shared with third parties**.

Shared User Info:

- 31 of the 41 apps (76%) without privacy policies,
- 19 of 24 apps (79%) with privacy policies
- 56 of 65 apps (86.2%) placed tracking cookies;

Consent for RWD

Retrospective Data Reviews

Current regulations sufficient

Waiver of informed consent and HIPAA authorization

Prospective Pragmatic Trials– Need Consent

Learn from Broad Consent for Biospecimen Banking

Broad Consent: Get consent use of all medical information

- Built in oversight mechanisms like IRBs
- People very supportive of use of their data – some have objections to use by for-profit companies. Would need to address this in consent

Grady C, Berkman B, Brock D, Cook-Deegan R, Fullerton S M, Greely, H, Hansson M, Hull S, Kim S, Bernard L, Pentz RD, Rodriguez L, Eckstein L, Weil C, Wendler D, Wilfond B. “Broad Consent for research with Biological Samples: Workshop Conclusions; America Journal of Bioethics. 2015;15(9):34-42.

Warner et al Unpublished data

Not all ethicists agree– No Consent or Opt out

People have a duty to participate in providing RWD based on "Love thy Neighbor" and the fact that this would enhance the public good and individuals do have public responsibility.

Rhodes R. "Love Thy Neighbor: Replacing Paternalistic Protection as the Grounds for Research Ethics" *AJOB*; 15(9) (2015): 49-51

Broad consent is not truly informed and is not practical in the busy clinic setting. Opt out is sufficient. Concerns are overblown

Botkin J. "Crushing Consent Under the Weight of Expectations" *AJOB*; 15(9) (2015): 47-49.

Consent in “Seamless” Drug Development

Each cohort has its own consent

1.Early cohorts enroll those with no SOC options.

2.Later cohorts expand to those with treatment options

3.The consents must make the alternatives clear and delineate the risks and benefits for that cohort

Theoret et al, *CCR Focus*

4. Early efficacy data should be shared

Prowell et all, NEJM