

Experience from an HDACi trial: implications on ethics and patient expectations

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Vorinostat: the context in 2010

- Unclear if “activating” virus would lead to virological failure
- Short and long term effects of drug itself
- Effects on other viruses – CMV, EBV, HERV
- Understanding of the science of cure research limited amongst clinicians and community
 - “Activating” virus was “bad”
 - “Activating” virus was “immune activation”
 - Should this first be done in animal models?

What did we do?

■ Partnership with NAPWHA

- membership on protocol steering committee and DSMB
- Development of patient materials and consent with a focus on risks up front

■ Community engagement

- Education through community forums (x3) and publications in community papers

■ Clinician education

- Multiple forums with high case load family physicians and hospital clinicians

Survey of study participants: 2013

Question

Response

How well have your questions or concerns been answered during the study (e.g. side effects)?

On a scale of 0 to 100 how satisfied have you been with your overall experience in this study?

Would you consider enrolling into a similar study in the area of HIV cure if approached?

Would you consider enrolling into a similar study if it was not in the area of HIV cure if approached?

Participant's priorities on outcomes of cure research

No longer need to see a doctor

Stopping HIV medications

**Being considered as a person
not infected with HIV**

Not getting HIV a second time

Not passing virus onto others

Managing expectations in 2013

The Telegraph

**Danish breakthrough
for HIV cure expected
'within months'**

April 29th., 2013

Conclusions

- Current and future cure studies do and will carry a wide range of **risk** and **complexity**
- Decisions on **acceptable risks** requires partnerships with community, regulatory and IRB processes
- Community **engagement** key to clinical trials in the field moving forward
- Managing **expectations** of cure research requires a broader strategy engaging both **community** and **general** media