Industry Collaboration & Regulatory Issues

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IAS 2013 Towards an HIV Cure Symposium
1. Are special informed consent procedures needed for cure related research?

2. Should the pharmaceutical industry receive special incentives for cure related research (incl. collaborations)?

3. What are some of the issues for regulatory authorities in fostering cure related research?
Are informed consent procedures good enough?

Research suggests that:

• Participant comprehension after standard consent process is often inadequate.

• Participant recall of informed consent content drops off over time.

• Participants under-estimate the harms/risks and overestimate the benefits when self-interest or compensation is high.

David Evans, Project Inform
Are special informed consent procedures needed for cure related research?

- Research regulatory authorities - responsibility to ensure individuals make fully informed and voluntary decisions.

- Developing and developed settings – differences in ethic review boards, regulatory authorities and support levels for research participants.

- Pharma, medical providers and PWHIV advocates - responsibilities to study participants.

- ?? Special Informed consent procedures just for HIV cure research.

- What is crucial is the stuff that goes on leading up to signing the informed consent – and ongoing.

- Good informed consent is optimized when there is broader community awareness fostered by researchers, pharma, regulatory authorities (example: Vorinostat study)
Topics to discuss

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3. What are some of the issues for regulatory authorities in fostering cure related research?
Incentives? Depends.
- Government grants, tax breaks – pharma profit levels.
- Pleasing that some pharma substantially investing in cure related research. Others are not and less engaged.
- Dr Steve Deeks: “Break down cultural and legal barriers so that academics can work with companies – and companies work with each other – in a team approach to conquering HIV.”
- Multiple barriers to cure - combination of drugs and interventions needed – pharma collaboration critical.
- Intellectual property complexities and sensitivities - repeatedly.
- No quick solution – dialogue with advocates, pharma, regulatory bodies, scientists, ethicists.
- IAS is well placed to play a convening role for best practice, global cure research and fostering collaboration.
- DARE Program – good model of public and private (cooperation).
- NIH – an arm of government - already very very engaged with DARE.
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What are some of the issues for regulatory authorities in fostering cure related research?

- May not always be the business of regulatory authorities to foster cure research.

- The role of the regulatory authority is to be clear about what their criteria is for approving treatments and to work with pharma and researchers about what is necessary to gain timely regulatory approval.

- But fostering cure research is a role of governments.

- Many countries have some government agency that is responsible for promoting high standard scientific research (e.g. NHMRC), and these are the bodies we need to be engaging with.

- Cost effectiveness of cure treatments – a critical issue for governments, regulatory agencies, health systems.

- Regulatory authorities may well approve treatments which provide a cure, but the cost may make this out of reach for the majority. They may also approve treatments which will only work in specific populations.

- To end the epidemic – the cure (s) are going to need to be cost-effective.
International commitments – cure research

• 2011 United Nations Political Declaration on HIV/AIDS.

• All countries committed to accelerating investment in cure research.

• All countries committed to ensuring the highest ethical standards.

• ?? How will countries meet these commitments.

• ?? What is the leadership and framework needed.