Patient input into benefit/risk issues during drug development

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Proposed principles

- Industry supports a consultative relationship between patients and industry
- Patient input adds broader perspectives on specific disease burden and patient expectations
- Informed patients are able to provide more valuable input
  - Bi-directional exchange – dialogue not monologue
  - Patient view of “acceptable risk” may differ from others’ views

Proposed principles (continued)

- A spectrum of mechanisms exist for obtaining patient input; some have a stronger scientific basis than others
- We are still learning which mechanisms are most valuable; pilot projects are needed
- Many constituents have an advisory role in the drug development and evaluation process, including medical specialists and patients
- Patient voice is important, yet the decision in the drug approval process rests with the regulators

Examples & Discussion

Conclusion

- Patient input is very important to understand the patient perception of benefits and risks
- Many examples of patient involvement in drug development exist
- We are all still learning together, which mechanisms are most valuable and pilot projects are needed
- Companies have regulatory restrictions on how to interact with patients in a bi-directional way
- Since informed patients provide the best input, modifications of some of the restrictions may be desirable