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WIISTDIA: Why Is it so Darn Difficult to Get More Imaging Drugs? -- A Glimpse on Approval, Trials, Costs, Safety, Generics & PMA

This presentation will introduce the medical, economic, technology and regulatory landscape facing the development of imaging products from laboratory to clinic (with an emphasis on MRI and slight USA-EU bias).

1. Description of imaging agents for the different imaging modalities.
2. History of currently available imaging agents and some of the issues that have faced the development of imaging agents. Examples of Iron Oxide products and FDG.
3. Description of the Drug Development Chain: The role of invention, commercialization, regulatory needs and clinical practice.
4. Commercialization is one of key barriers, but a necessary step in the wide availability of imaging drugs. The consideration of developing and selling a imaging product is not unlike most other commercial endeavors and involves the assessment of market needs, risks, and financial consideration. It does however carry some unique challenges. The various components of commercialization will be described with some examples. (patents, supply chains, market value etc)
5. One of the key aspects of commercialization is regulatory approval. Regulatory requirements vary for the various countries. Some of the processes for USA and EU region will be described.
6. An example of a clinical development for a typical MRI drug will be described. The role of well controlled clinical trials, proper dose determination and clinical indications.
7. The role of associated device and the rapidly changing technology will be described.
8. What happens to drug availability when patents expire The implications of "Generic drugs" will be described.