Managing Uncertainty over the Life Cycle of Drug Development and Use Enhancing Adaptability and Flexibility in Pharmaceuticals Innovation

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Introduction

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Recent Developments in Europe

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Recent Developments in the United States

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Industry and Patient Perspectives on Recent Developments

CRISES	RESPONSES
Thalidomide	Approval based on efficacy/safety evidence from trials Strengthen adverse effects reporting (AERS/VARS)
Accutane™ and Vioxx™	Controls to limit known risks (REMS/RMS) Increased attention to safety and risk management Strengthen active & passive surveillance (Sentinel)
HIV, Cancer	Accelerated Approval/Conditional Marketing Authorization Use of un-validated biomarkers
Licensing backlog	Prescription Drug User Fee Act (PDUFA)

EVOLUTIONARY CHANGES

Genetic revolution and splintering of indications

Increasing late stage failures and rising development costs

Rising drug prices

Demand for evidence based treatment and payment

Patient demand for voice

Improving (but still flawed) electronic health records

Rising liability concerns with early patient exposure

Globalization of trials, procurement and production

LEARNING AND INNOVATION ?

Health Canada

Progressive Licensing

US Food and Drug Administration

Breakthrough Product Designation

Specialized Medical Use

Patient Focused Drug Development

Pharmaceutical Quality Metrics

Formal Benefit-Risk Assessment

European Medicines Agency

Roadmap to 2015

Pharmacovigilance Legislation

Adaptive Licensing Pilots

Public access to data on trials