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When science and regulatory action meet reality: barriers and critical succes factors to managing risk

Some reflections

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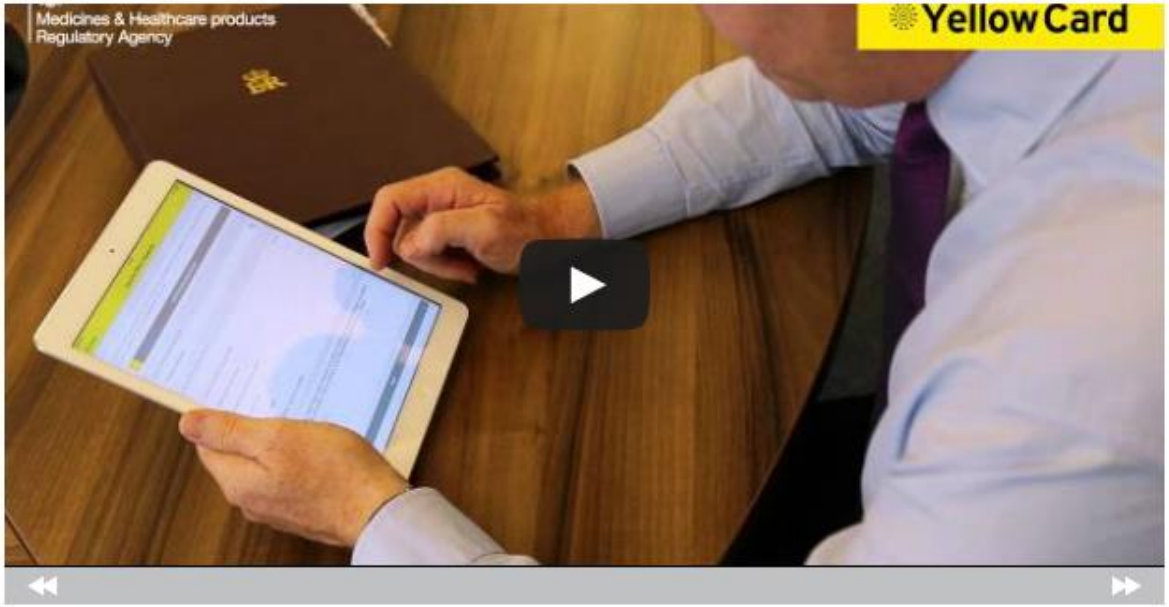
FEASIBILITY



Feasibility

- Many 'new' tools
  - E-mails
  - CME
  - CPOE/CDSS
  - **Mobile apps**
  - Web-based tools
- And older
  - DHPC
  - Information brochures
- Or restrictive
  - PPP
  - Conditional dispensing
  - Informed consent

Therapeutics and Clinical Risk Management
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PERSPECTIVES

Integrating risk minimization planning throughout the clinical development and commercialization lifecycle: an opinion on how drug development could be improved

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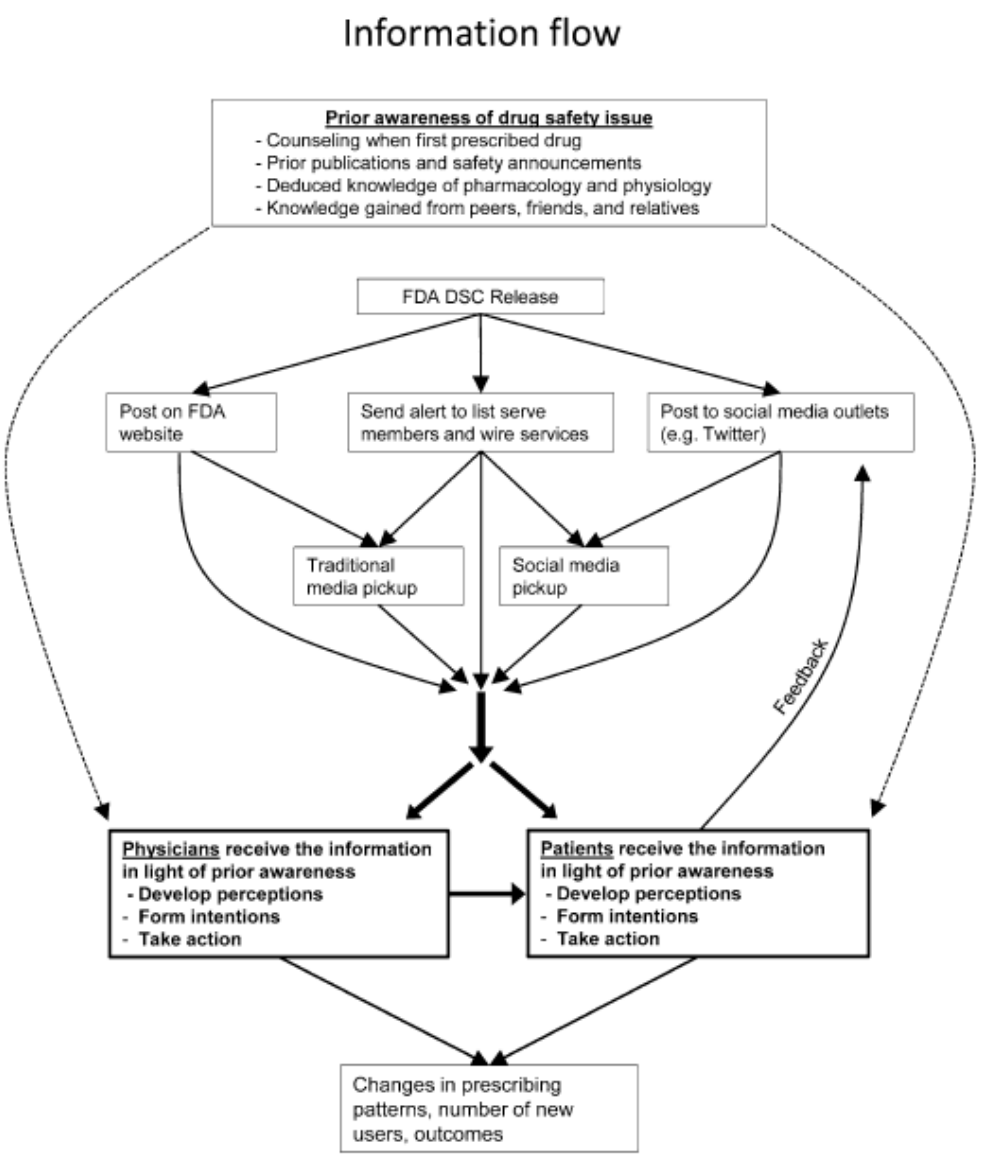
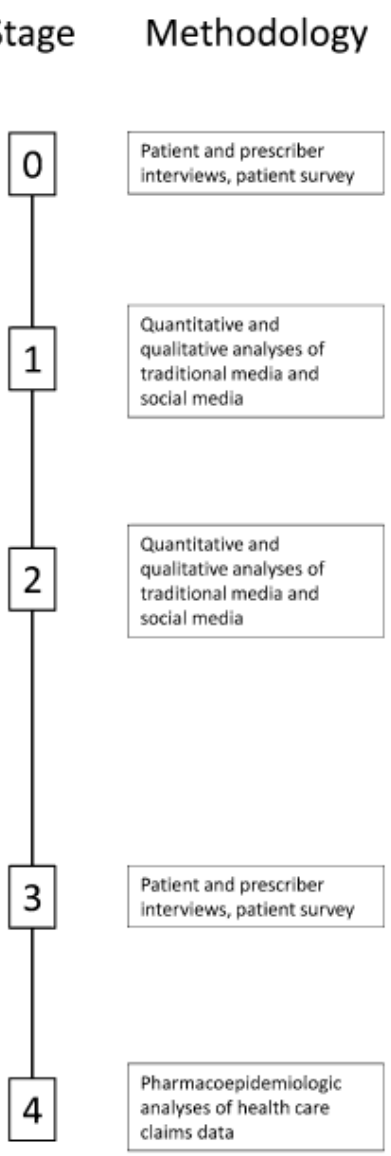
Abstract: Pharmaceutical risk minimization programs are now an established requirement in the regulatory landscape. However, pharmaceutical companies have been slow to recognize and embrace the significant potential these programs offer in terms of enhancing trust with health care professionals and patients, and for providing a mechanism for bringing products to the market that might not otherwise have been approved. Pitfalls of the current drug development process include risk minimization programs that are not data driven; missed opportunities to





Banerjee et al 2014 Drug Saf
Kesselheim et al 2015 Drug Saf

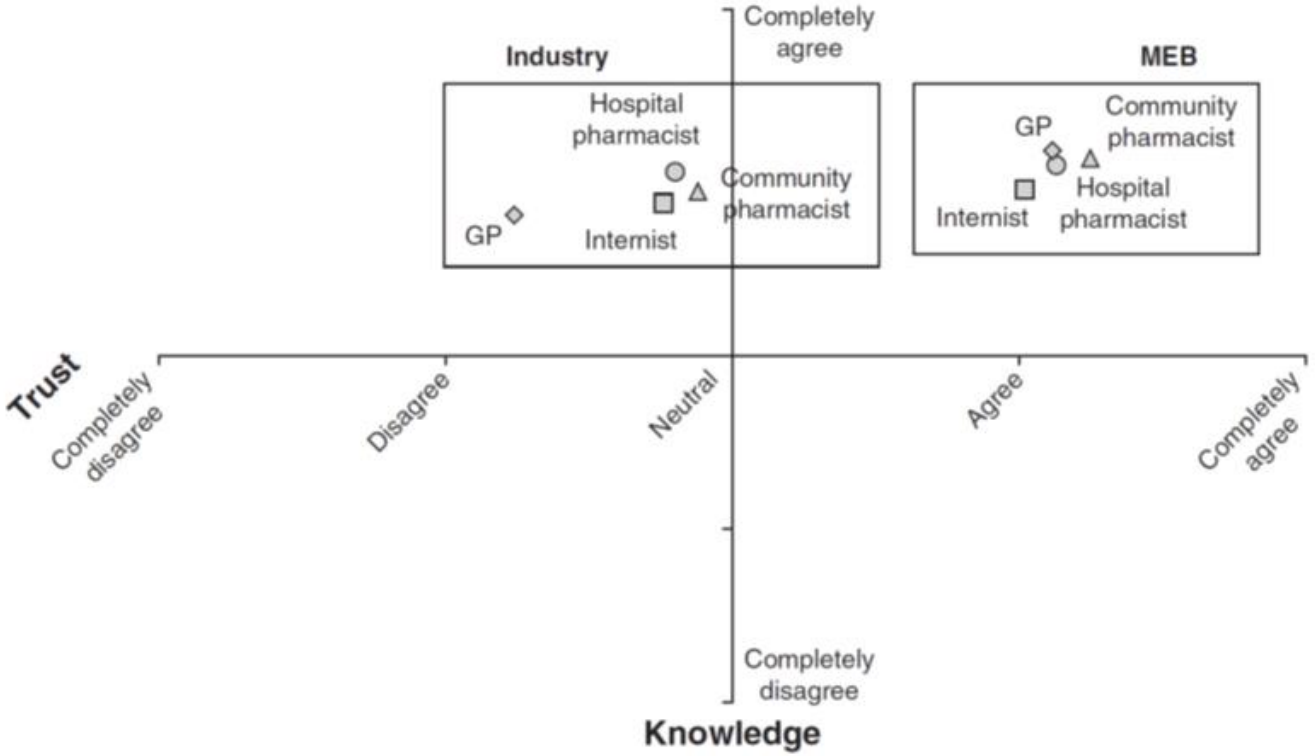


Fig. 1. Trust and knowledge attributed to the Dutch Medicines Evaluation Board/pharmaceutical industry.

ENGAGING STAKEHOLDERS

Piening 2012 Drug Saf