POZNÁMKY

1. kapitola: Chybějící data

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na jeho pronesení a naopak nepřímo úměrná nákladům vynaloženým na jeho vyvrácení. Neudělali jsme to a dokud to neuděláme, bude popis naší konverzace jediným odkazem na tuto zajímavou myšlenku.
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74. Tento příběh je vylíčen napříč různými publikacemi od Cochraneova týmu a zdejší vysvětlení je převzato z jejich práce, publikovaných odpovědí Roche a diskusí s Cochraneovým týmem. Nejlepší místo, kde se dozvíte první polovinu tohoto příběhu, je následující článek: Doshi P. Neuraminidase inhibitors – the story behind the Cochrane review. BMJ. 2009; 339. A pro druhou polovinu doporučuji tento volně přístupný článek: Doshi P., Jefferson T., Del Mar C. (2012) The Imperative to Share Clinical Study Reports: Recommendations from the Tamiflu Experience. PLoS Med 9(4): e1001201. doi:10.1371/journal.pmed.1001201 http://bit.ly/HIbwqO
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2. kapitola: Odkud se berou nové léky?

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and the Global Search for Human Subjects. 1st ed. Princeton University Press; 2009.
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3. kapitola: Podivná regulace léčiv

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32. NICE, 'CG17 Dyspepsia: full guideline,' Guidance/Clinical Guidelines, http://guidance.nice.org.uk/CG17/Guidance/pdf/English. Ale také, kdyby vám směrnice NICE a jeho odkazy nestačily (pocházejí z roku 2004), věnujte prosím hodinku svého času procházením dalších novějších výzkumů. Zjistíte, že na esomeprazolu nebylo nalezeno nic magického.
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36. Tady bych měl přiznat svůj zájem: sedím ve finanční radě, která řeší přesně tuto otázku každé čtvrtletí pro program NHS „Hodnocení zdravotnické technologie". Tento proud financování je určen speciálně na odhalování výzkumů, které je zapotřebí udělat, ale které nebude financovat žádná firma, na porovnávání jedněch léků s jinými, a pokud si jste vědomi nějakých významných oblastí, kde nevíme, který ze dvou významných léků je lepší, měli byste si tu podat žádost (nebo pokud jste líní, napište mi e-mail).
37. Jestli vás hodně zajímá toto téma, v tomto detailu tu spočívá vážný problém. Mezinárodní společnost bulletinů o lécích, která zastupuje akademiky a farmaceuty vytvářející přívětivá shrnutí údajů pro lékaře, po pět let vedla kampaň za to, aby získala přístup k čemusi jménem Signal, publikaci WHO, která hovoří o otázkách bezpečnosti léků vzešlých z nezpracovaných dat z kazuistik. WHO neustále odmítala a trvala na tom, že zprávu smí vidět pouze „národní zdravotnické úřady", ale v roce 2012 změnila názor a nyní plánuje širší přístup i pro jiné nezávislé skupiny. Tím však sága bohužel nekončí. Farmaceutickým firmám se stále povoluje prvotní přístup, aby mohly „číst a komentovat" před publikací. A Signal je pouze publikace popisující výsledky, nikoli jednotlivé případové studie, které jsou shromážděny v tzv. VigiBase, jež zůstává nadále tajná. Údaje z UK a USA jsou dostupné snáz, ale data EU, jak asi čekáte, nikoliv. Víc si můžete přečíst v tiskové zprávě a na webové stránce ISDB: http://www.isdbweb.org/publications/view/pharmacovigilance-data ('Broadening access to signal is a positive step, but access to VigiBase is also needed', ISDB, 15. únor 2012).
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