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Clinical Trial Data Transparency

Making progress but still a way to go

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HAI & Public Eye Conference on Clinical Drug Trials

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Health Action International

- Non-profit, improves access & rational use of medicines via research & advocacy
- Expert members in more than 70 countries (130 in Europe)
- Member of EMA's PCWP & in 'official relations' with WHO
- No pharma funding; funded by foundations & governments

Takeaway Messages

1. Clinical trial (CT) data transparency crucial to protect people's health
2. Significant pro-transparency initiatives in the EU
3. But still a way to go to achieve full transparency

Health & Human Rights

"…the highest attainable standard of **health** is one of the fundamental rights of every human being."

"It is an inclusive right extending not only to timely and appropriate health care, but also to the underlying determinants of health, for example, **access to health information**…"

— World Health Organization

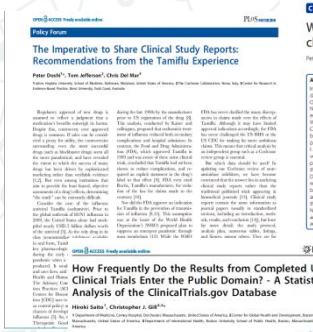
The Risk to Health

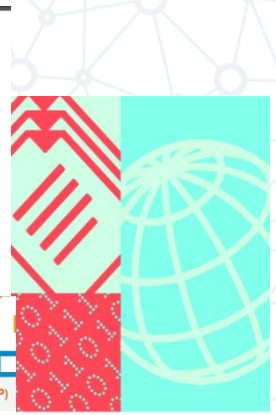
- Lack of CT data transparency
  - Situation of ‘information asymmetry’ widely abused by pharmaceutical companies
- Publication bias in CT & selective reporting of results
  - Marketing strategy: present treatment in most favourable way
  - Overestimation of treatment benefits & underestimation of risks
  - Threatens patient safety

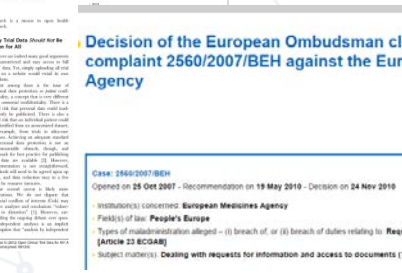
Transparency Protects Health

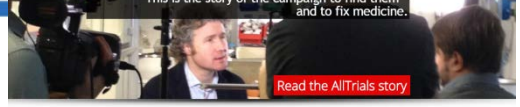
- Mandatory CT data disclosure can help
  - Improve informed treatment decision-making
  - Address publication & reporting bias
  - Facilitate independent review
  - Prevent unnecessary CT duplication and participants' exposure to risk

Spotlight on CT Data Transparency









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Regulatory Initiatives in Europe

- EU Clinical Trials Regulation (2014)
  - All drug trials in Europe registered before starting
  - Summary results published within a year of trial's end with layperson's summary
  - 'Clinical Study Reports' (CSRs) published after conclusion of marketing authorisation procedure
  - In general, information in CSRs should not be considered 'commercially confidential'
  - Overriding public interest disclosure

Regulatory Initiatives in Europe

- EMA Policy on Publication of Clinical Data for Medicinal Products for Human Use (2014)
  - Clinical data made available proactively
  - Phase 1: Publication of clinical reports

The Road to Full Transparency

Are we there yet?

Barriers to Full Transparency

- Must remain vigilant
  - Redactions on grounds of ‘commercial confidentiality’
  - Anonymisation techniques undermining scientific usefulness of CT data

Anonymisation Techniques

CRTN/Pt. No.	Age yr	Sex	Weight kg	Height cm	Race	Treatment Start End
[redacted]3030	34	F	65	[redacted]	CAUCASIAN	18JAN2001 22JAN2001
[redacted]3032	13	F	81	[redacted]	CAUCASIAN	22JAN2001 26JAN2001
[redacted]3033	37	F	76	[redacted]	CAUCASIAN	13FEB2001 17FEB2001
[redacted]3035	43	M	98	[redacted]	CAUCASIAN	30JAN2001 04FEB2001
[redacted]3045	20	M	57	[redacted]	CAUCASIAN	30JAN2001 04FEB2001
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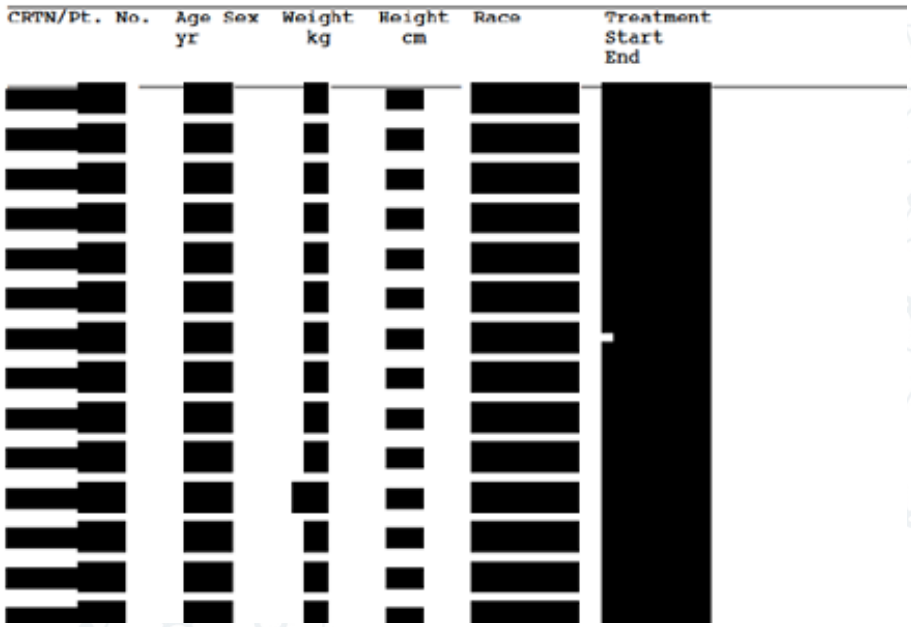
Line listing from Tamiflu trial WV16277 (Research Report No. 1005291) redacted by Roche for public release



Line listing from Tamiflu trial WV16277 (Research Report No. 1005291) redacted according to TransCelerate guidance

El Emam, K., Jefferson, T. & Doshi, P. (2015) The release of regulatory documents under EMA policy 0070: Now you see them, now you don't. *BMJ Blogs.*

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Barriers to Full Transparency

- Also, what about…
  - Unregistered trials & unreported results?
  - Full reports of non-commercial trials/not submitted for marketing authorisation?
  - Availability of individual participant data?
  - Monitoring & enforcement?

Summary

1. CT data transparency crucial to protect people's health
2. Significant pro-transparency initiatives in the EU
3. Still a way to go to achieve full transparency

Thank You

- With support from:
  - This presentation received funding under an operating grant from the European Union's Health Programme (2014–2020)
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