Data sharing: principles, approaches and costs

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Why share IPD?

Ethical Obligation

Journal requirements

Funder requirements

Reduce waste and burden on patients

Value of IPD

ELSEVIER

Journal of Clinical Epidemiology 69 (2016) 40–50

Journal of Clinical Epidemiology

Multivariate meta-analysis of individual participant data helped externally validate the performance and implementation of a prediction model

Kym I.E. Snell[a], Harry Hua[b], Thomas P.A. Debray[c,d], Joie Ensor[e], Maxime P. Look[f], Karel G.M. Moons[c,d], Richard D. Riley[e,*]

Osteoarthritis and Cartilage 24 (2016) 1143–1152

Osteoarthritis and Cartilage

OARSI OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

The OA Trial Bank: meta-analysis of individual patient data from knee and hip osteoarthritis trials show that patients with severe pain exhibit greater benefit from intra-articular glucocorticoids

ELSEVIER

Journal of Clinical Epidemiology 68 (2015) 1325–1335

Journal of Clinical Epidemiology

How individual participant data meta-analyses have influenced trial design, conduct, and analysis

Jayne F. Tierney[a,*], Jean-Pierre Pignon[b], Francois Gueffyier[c,d], Mike Clarke[e], Lisa Askie[f], Claire L. Vale[a], Sarah Burdett[a], On behalf of the Cochrane IPD Meta-analysis Methods Group

Cochrane Library

Cochrane Database of Systematic Reviews

Antiepileptic drug monotherapy for epilepsy: a network meta-analysis of individual participant data (Review)

Nevitt SJ, Sudell M, Weston J, Tudur Smith C, Marson AG

BMJ 2013;347:f6927 doi: 10.1136/bmj.f6927 (Published 2 December 2013)

VIEWS & REVIEWS

OPEN DATA CAMPAIGN

Why did it take 19 months to retrieve clinical trial data from a non-profit organisation?

Asbjørn Hróbjartsson *The Nordic Cochrane Centre, Copenhagen, Denmark*

Jaspers and Degraeuwe *Systematic Reviews* 2014, **3**:97
http://www.systematicreviewsjournal.com/content/3/1/97

SYSTEMATIC REVIEWS

LETTER Open Access

A failed attempt to conduct an individual patient data meta-analysis

Gerald J Jaspers and Pieter LJ Degraeuwe*

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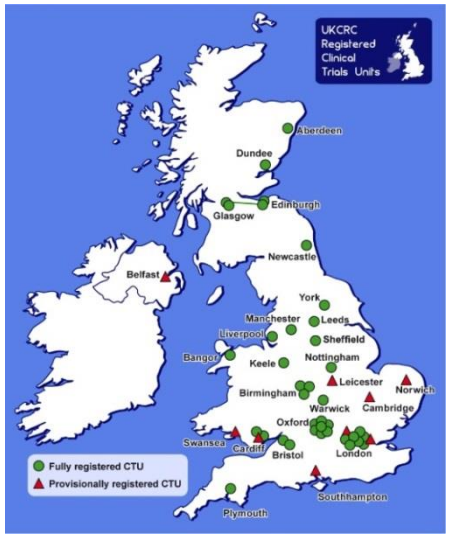
CTU survey



ELSEVIER

Journal of Clinical Epidemiology ■ (2015) ■

Journal of Clinical Epidemiology

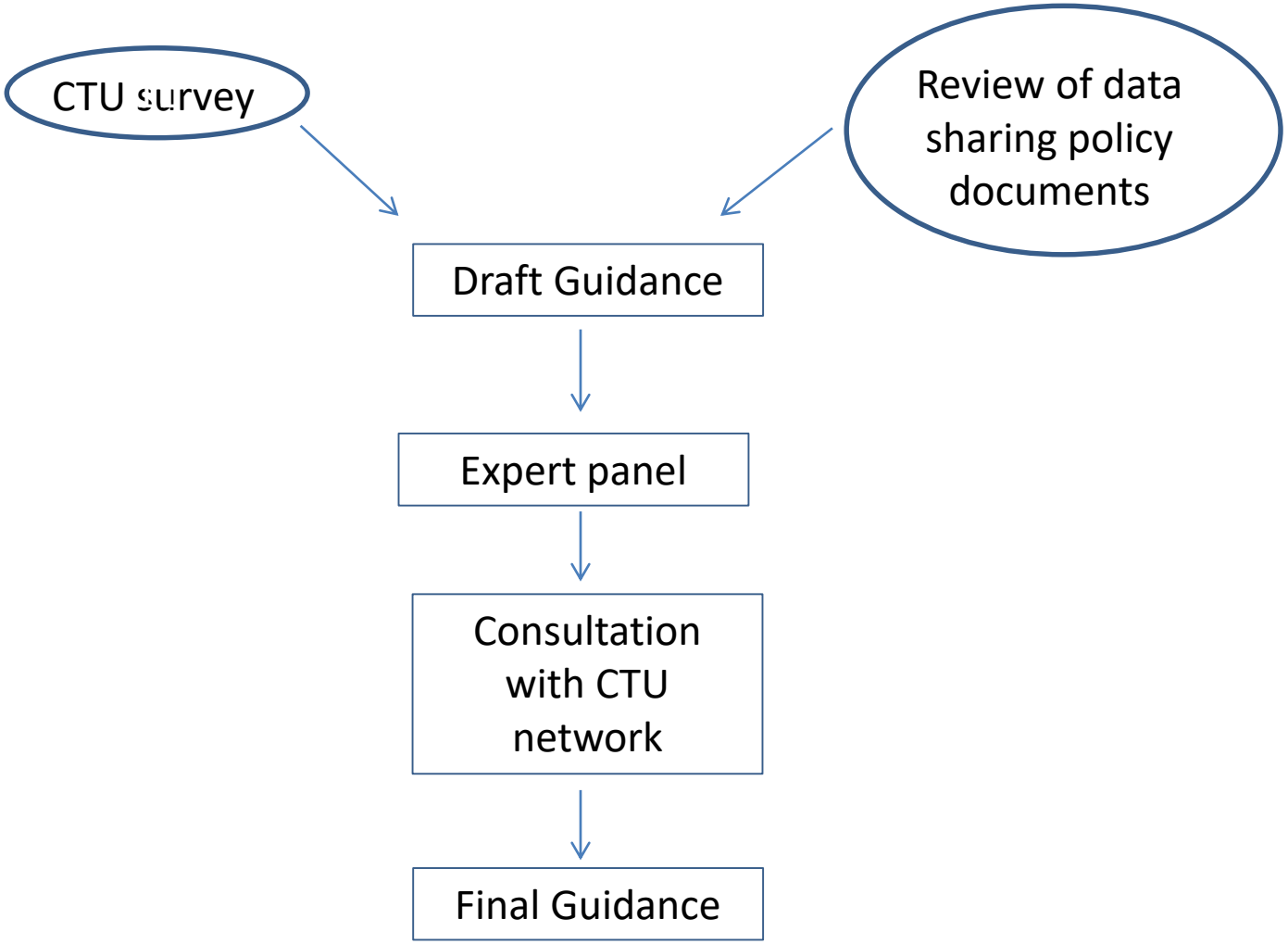
ORIGINAL ARTICLE

UK publicly funded Clinical Trials Units supported a controlled access approach to share individual participant data but highlighted concerns

Carolyn Hopkins[a], Matthew Sydes[b], Gordon Murray[c], Kerry Woolfall[d], Mike Clarke[e], Paula Williamson[a], Catrin Tudur Smith[a,*]

- 23 (51%) of **UK CRC registered CTUs** responded to the survey
- Supportive of sharing in a controlled access approach
- Concerns: Misuse of data, resources, loss of IP

Guidance


CTU survey
Review of data sharing policy documents
Draft Guidance
Expert panel
Consultation with CTU network
Final Guidance

Guidance

Tudur Smith *et al. BMC Medicine* (2015) 13:298
DOI 10.1186/s12916-015-0532-z

BMC Medicine

GUIDELINE Open Access

How should individual participant data (IPD) from publicly funded clinical trials be shared?

C. Tudur Smith[1*], C. Hopkins[1], M. R. Sydes[2], K. Woolfall[3], M. Clarke[4], G. Murray[5] and P. Williamson[1]

Endorsed by Cancer Research UK, MRC Methodology Research Programme Advisory Group, Wellcome Trust and the Executive Group of the UK CRC Registered CTUs Network. The National Institute for Health Research (NIHR) has confirmed it is supportive of the application of this guidance.

http://www.network-hubs.org.uk/files/7114/3682/3831/Datasharingguidance2015.pdf

Good practice at CTU/sponsor level

- *A data sharing policy should be developed by the CTU outlining*
  - Scope
  - Data request process (approval within 3 months, all requests and their outcomes publicly available)
  - Data release process
  - Data use agreement
- *Resources*
  - Funds requested from trial funders as part of initial trial grant applications
  - Reasonable costs may be recovered from data requesters if appropriate (not profit generating)
  - Host organisations to provide funds for ongoing support of a data sharing system

Good practice at trial level

- *Prior to trial funding*
  - Identify data sharing stakeholders and highlight the data sharing policy
  - Understand the trial funder's policy and include funds in grant applications where appropriate

- *During trial set-up*
  - Identify roles and responsibilities for data sharing
  - Include plans for data sharing in the protocol and data management plan
  - Include a data sharing statement in the consent form and patient information leaflet
  - Annotate the complete set of blank Case Report Forms (CRFs)

- *End of trial*
  - Prepare 'data pack' ready for sharing. This would typically include

    Anonymised datasets, protocol with amendments, blank CRFs, dataset specifications (or annotated CRFs) including data variable amendments

Tudur Smith *et al. Trials* (2017) 18:319
DOI 10.1186/s13063-017-2067-4

Trials

RESEARCH Open Access

Resource implications of preparing individual participant data from a clinical trial to share with external researchers

Catrin Tudur Smith[1*], Sarah Nevitt[1], Duncan Appelbe[1], Richard Appleton[2], Pete Dixon[3], Janet Harrison[1], Anthony Marson[3], Paula Williamson[1] and Elizabeth Tremain[4]

SANAD and MENDS trials

The SANAD study of effectiveness of carbamazepine, gabapentin, lamotrigine, oxcarbazepine, or topiramate for treatment of partial epilepsy: an unblinded randomised controlled trial

Anthony G Marson, Asya M Al-Kharusi, Muna Alwaidh, Richard Appleton, Gus A Baker, David W Chadwick, Celia Cramp, Oliver C Cockerell, Paul N Cooper, Julie Doughty, Barbara Eaton, Carrol Gamble, Peter J Goulding, Stephen J L Howell, Adrian Hughes, Margaret Jackson, Ann Jacoby, Mark Kellett, Geoffrey R Lawson, John Paul Leach, Paola Nicolaides, Richard Roberts, Phil Shackley, Jing Shen, David F Smith, Philip E M Smith, Catrin Tudur Smith, Alessandra Vanoli, Paula R Williamson, on behalf of the SANAD Study group.

Lancet 2007; 369: 1000–15

BMJ

RESEARCH

BMJ 2012;345:e6664 doi: 10.1136/bmj.e6664 (Published 5 November 2012)

Melatonin for sleep problems in children with neurodevelopmental disorders: randomised double masked placebo controlled trial

P Gringras *professor in paediatric sleep and neurodisability*[1], C Gamble *reader in medical statistics*[2], A P Jones *senior statistician*[2], L Wiggs *reader in psychology*[3], P R Williamson *director of medicines for children research network clinical trials unit*[2], A Sutcliffe *reader in general paediatrics*[4], P Montgomery *reader in psychosocial intervention*[5], W P Whitehouse *clinical associate professor*[6], I Choonara *professor in child health*[7], T Allport *consultant paediatrician*[8], A Edmond *professor in community child health*[8], R Appleton *consultant paediatric neurologist*[9], on behalf of the MENDS Study Group

SANAD: n=2437

MENDS: n=146

SANAD 387 variables, 98 text
MENDS 650 unique variables, 150 text variables

SANAD - resources

	Statistician	Information Systems	Trial Management
Getting access	2.5	3	5
Anonymisation	32	0	0
Final data pack	1.5	0	0
Quality control	6	0	0
TOTAL hours	42	3	5

Estimated cost (SANAD)

Directly Incurred Staff Total	**£1,750**
Estimate of FEC	**£1,435**
Total project cost	**£3,185**

50 hours

MENDS - resources

	Statistician	Information Systems
Getting Access	1.5	6
Anonymisation	26	0
Final data pack	1	0
Quality control	5	0
TOTAL hours	33.5	6

Estimated cost (MENDS)

Directly Incurred Staff Total	**£1,397**
Estimate of FEC	**£1,143**
Total project cost	**£2,540**

39.5 hours

Is culture changing?

RESEARCH

Exploring changes over time and characteristics associated with data retrieval across individual participant data meta-analyses: systematic review

Sarah J Nevitt,[1] Anthony G Marson,[2] Becky Davie,[1] Sally Reynolds,[1] Lisa Williams,[1] Catrin Tudur Smith[1]

"… IPD retrieval rate across 760 published IPD meta-analyses … has not improved over time"

"IPD retrieval rate of the Cochrane Epilepsy Group has declined from 83% (up to 2005) to 65% (between 2012 and 2015)…."

"… reported reasons for lack of data availability have changed in recent years"

Final remarks

- Sharing clinical trial data
  - ethically and scientifically warranted
  - should be done responsibly and risk proportionally
  - barriers are not insurmountable
  - integrated into trial process

Thank you

Acknowledgements

Carolyn Hopkins, Matt Sydes, Kerry Woolfall, Mike Clarke, Gordon Murray, Paula Williamson, Sarah Nolan, Liz Tremain, Tony Marson, Duncan Appelbe, Richard Appleton

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NIHR funded cost project