D3: DELIVERING DIGITAL DRUGS

www.digital-drugs.org

Research Protocol

Valentina Lichtner

On behalf of the D3 team

LSE, 19 May 2015

The Health Foundation Inspiring Improvement

LSE The London School of Economics and Political Science

University of Leeds

Brunel University London

UCL

Digital Economy Transforming Business and Society

Acknowledgements

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Dr Tony Cornford Dr Panos Kanavos Dr Ela Klecun Dr Carsten Sorensen Dr Will Venters Dr Ralph Hibberd Dr Jane Dickson	*London School of Economics and Political Science*
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Valentina Lichtner	University of Leeds
Professor Nick Barber	*The Health Foundation*

Overview

- Drugs going digital: how we understand this
- How we research it: method and language (a ‘protocol’)
- Some reflections and future work

Introducing Digital Drugs…

- Our concern is with the changing nature of medical drugs (medicines) as they become encrusted with digital features and embedded in new data ecosystems.
- We ask *how, where* and *for whom* the digitalisation of the chain of supply and consumption of medical drugs (medicines) may create or add *value*, and the new or changed *work practices* and *business models* that develop.


12 CHEWABLE TABLETS
ADVANCE
MINT CHEWABLE TABLETS
sodium alginate
potassium bicarbonate
Heartburn and Indigestion
Long Lasting
5 000158 067745
12 CHEWABLE TABLETS
MINT CHEWABLE TABLETS
PATIENT INFORM
ON ADVANCE MI
Sodium
Potassium

Background

- Drugs and digitalisation

  - ❖ Active molecule, material delivery systems, informational resources for legitimation and use
  - ❖ Their use set within complex and elaborated work practices and institutional arrangements

  - ❖ The new Digital Drugs are just more so
  - ❖ Dependent on and substantially constituted by multiple digital representations and connections, with use and effectiveness strongly mediated through digital means.

Background

- A healthcare ‘imperative’

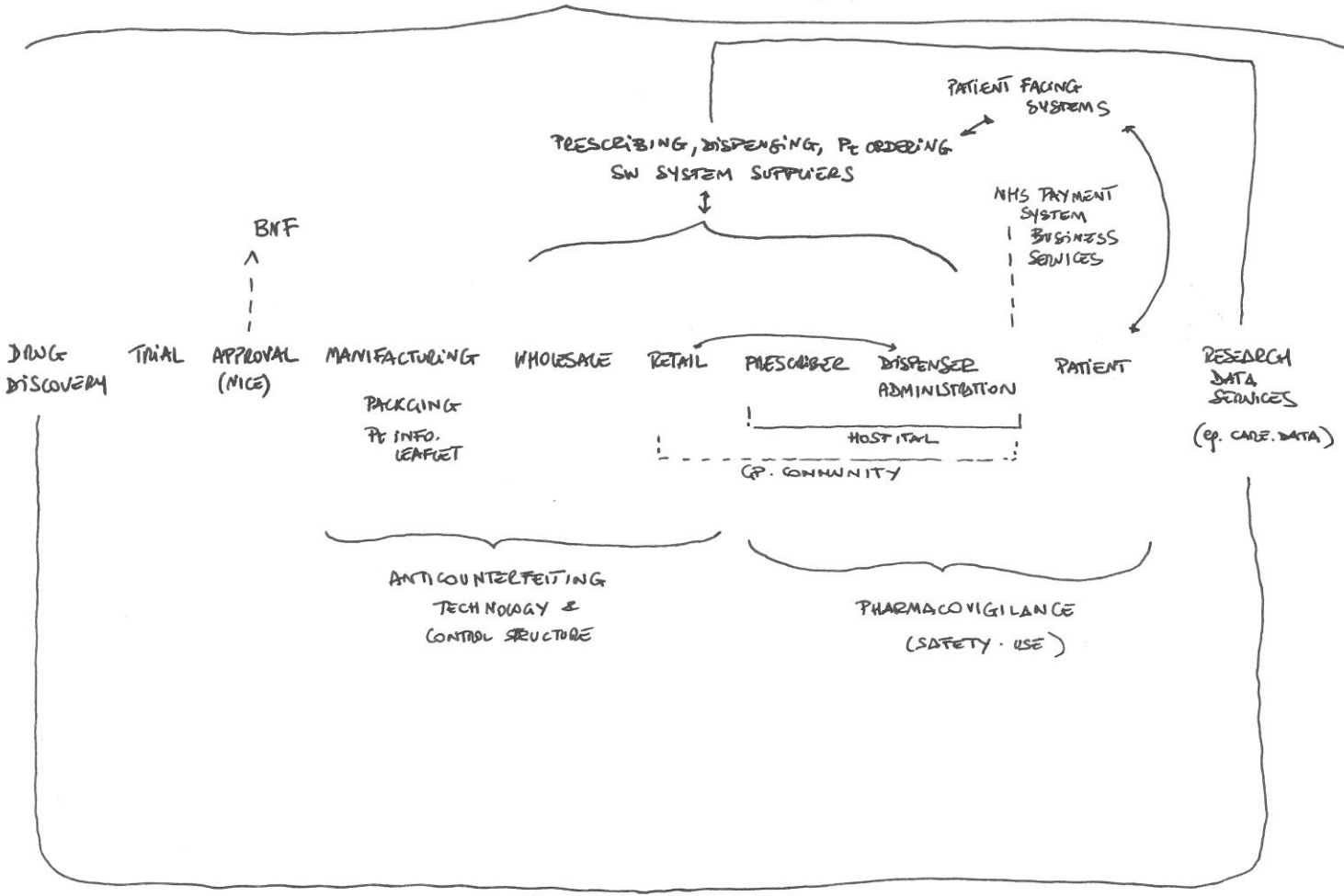
  - Our healthcare is built on using medicines - a primary means of providing care and a primary source of cost
  - Current expectations of new drugs, and of better ways to use the ones we have; more effect for less cost
  - A over a decade of digitization of drug-use data and related ICT systems e.g. electronic prescribing with decision support, robotic dispensing, prescription transmission, adherence technologies
  - More opportunities ahead: EHRs at scale, pharmacovigilance, $10 genome, stratified and personalised medicines etc.

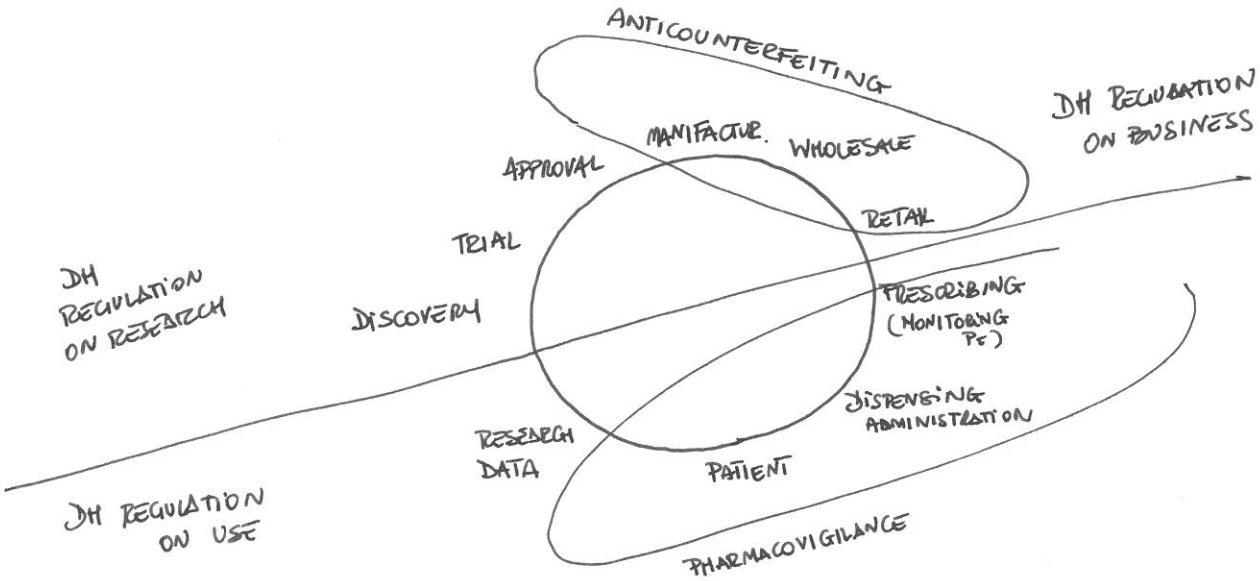
Theoretical Propositions (Hypotheses)

1. digitalisation is changing the materiality of the drug
2. digitalisation is changing the value of the drug
3. digitalisation is changing the assemblages that occur around and involving the drug
4. the drug is (or becoming, or returning to be?) an 'incomplete product'; the drug is (or is becoming) entangled with the digital, as a 'digital hybrid'

Theoretical influences

- *Changing as a sociomaterial process*
  (Petrakaki, Cornford et al. 2010)
- *Digital materiality* enmeshed within work practices
  (e.g. (Leonardi 2010, Yoo 2012))
- *Assemblages* - a question of emergence (emergent properties, generativity) in open systems – "the always-emergent conditions of the present"
  (Marcus and Saka 2006, De Landa 2002).
- *Digital business models* and their narrative and performative roles in mobilizing and explaining change
  (Christensen, Grossman et al. 2009)


DH REGULATION & NHS IT INFRASTRUCTURE & GOVERNANCE
PATIENT FACING SYSTEMS
PRESCRIBING, DISPENSING, Pt ORDERING SW SYSTEM SUPPLIERS
NHS PAYMENT SYSTEM
BUSINESS SERVICES
BNF
DRUG DISCOVERY
TRIAL
APPROVAL (NICE)
MANUFACTURING
WHOLESALE
RETAIL
PRESCRIBER
DISPENSER
ADMINISTRATION
PATIENT
RESEARCH DATA SERVICES
(eg. CARE. DATA)
PACKGING
Pt INFO. LEAFLET
HOSPITAL
GP. COMMUNITY
ANTICOUNTERFEITING TECHNOLOGY & CONTROL STRUCTURE
PHARMACOVIGILANCE (SAFETY · USE)


ANTICOUNTERFEITING
DH REGULATION ON BUSINESS
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APPROVAL
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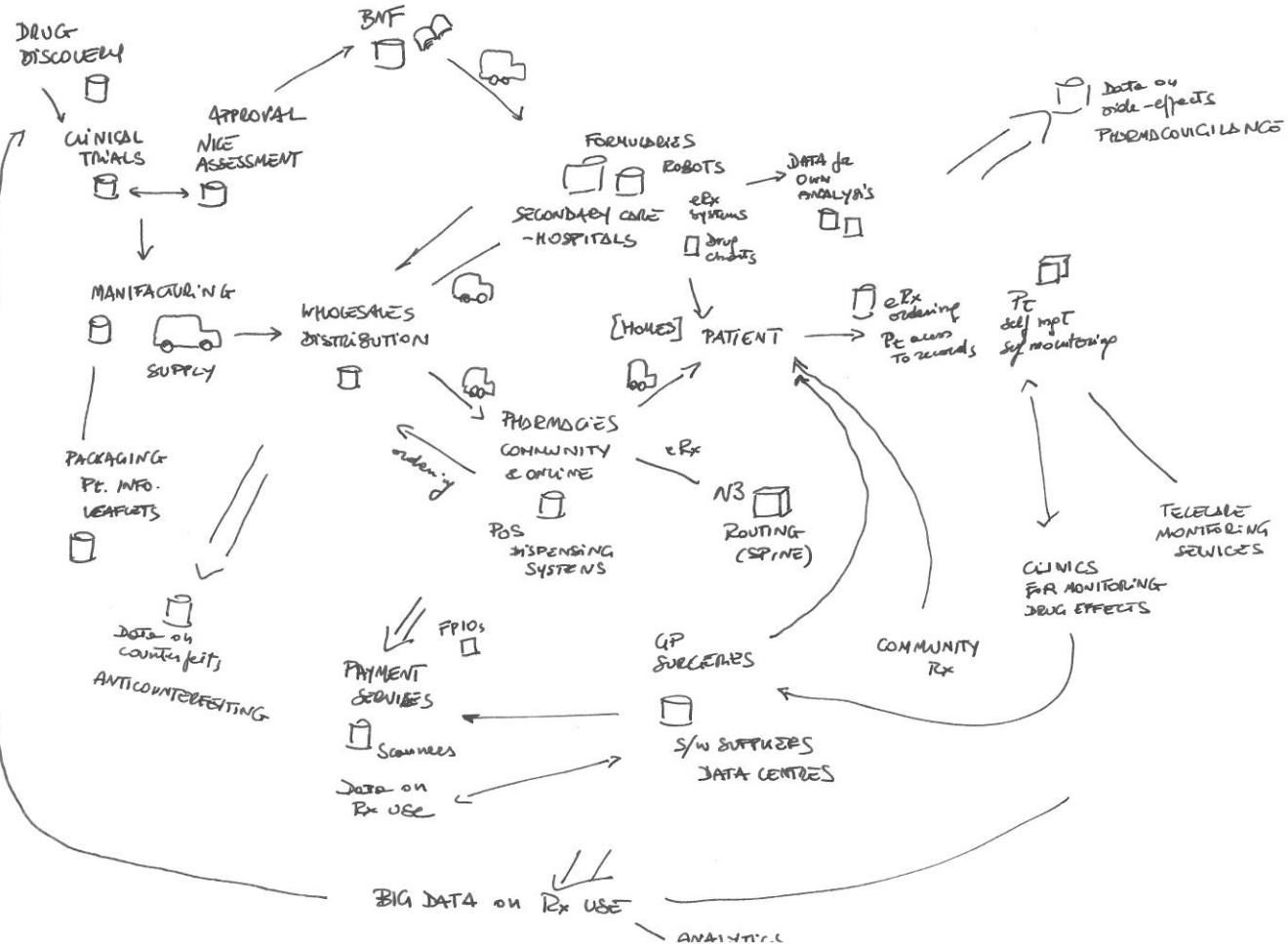
TRIAL
DH REGULATION ON RESEARCH
DISCOVERY
PRESCRIBING (MONITORING PT)
DISPENSING ADMINISTRATION
RESEARCH DATA
PATIENT
DH REGULATION ON USE
PHARMACOVIGILANCE


DRUG DISCOVERY
CLINICAL TRIALS
APPROVAL
NICE ASSESSMENT
BNF
FORMULARIES
ROBOTS
SECONDARY CARE - HOSPITALS
eRx systems
Drug charts
DATA for OWN ANALYSIS
Data on side-effects
PHARMACOVIGILANCE
MANUFACTURING
SUPPLY
WHOLESALES DISTRIBUTION
[HOMES]
PATIENT
eRx ordering
Pt access to records
Pt self mgt sx monitoring
PACKAGING
Pt. INFO. LEAFLETS
ordering
PHARMACIES COMMUNITY & ONLINE
eRx
NB ROUTING (SPINE)
POS DISPENSING SYSTEMS
TELECARE MONITORING SERVICES
CLINICS FOR MONITORING DRUG EFFECTS
Data on counterfeit
ANTICOUNTERFEITING
FPIOs
PAYMENT SERVICES
Scanners
GP SURGERIES
COMMUNITY Rx
S/W SUPPLIERS DATA CENTRES
Data on Rx use
BIG DATA on Rx USE
ANALYTICS


DRUG DISCOVERY
AD
CLINICAL TRIALS
DD
APPROVAL
NICE ASSESSMENT
DD DA
BNF
AD
FORMULARIES
ROBOTS
SECONDARY CARE - HOSPITALS
eRx systems
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DATA for OWN ANALYSIS
DA
DD AD
Data on side-effects
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[HOLES]
PATIENT
eRx ordering
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ordering
PHARMACIES COMMUNITY & ONLINE
POS DISPENSING SYSTEMS
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Data on counterfeits
ANTICOUNTERFEITING
FPIOs
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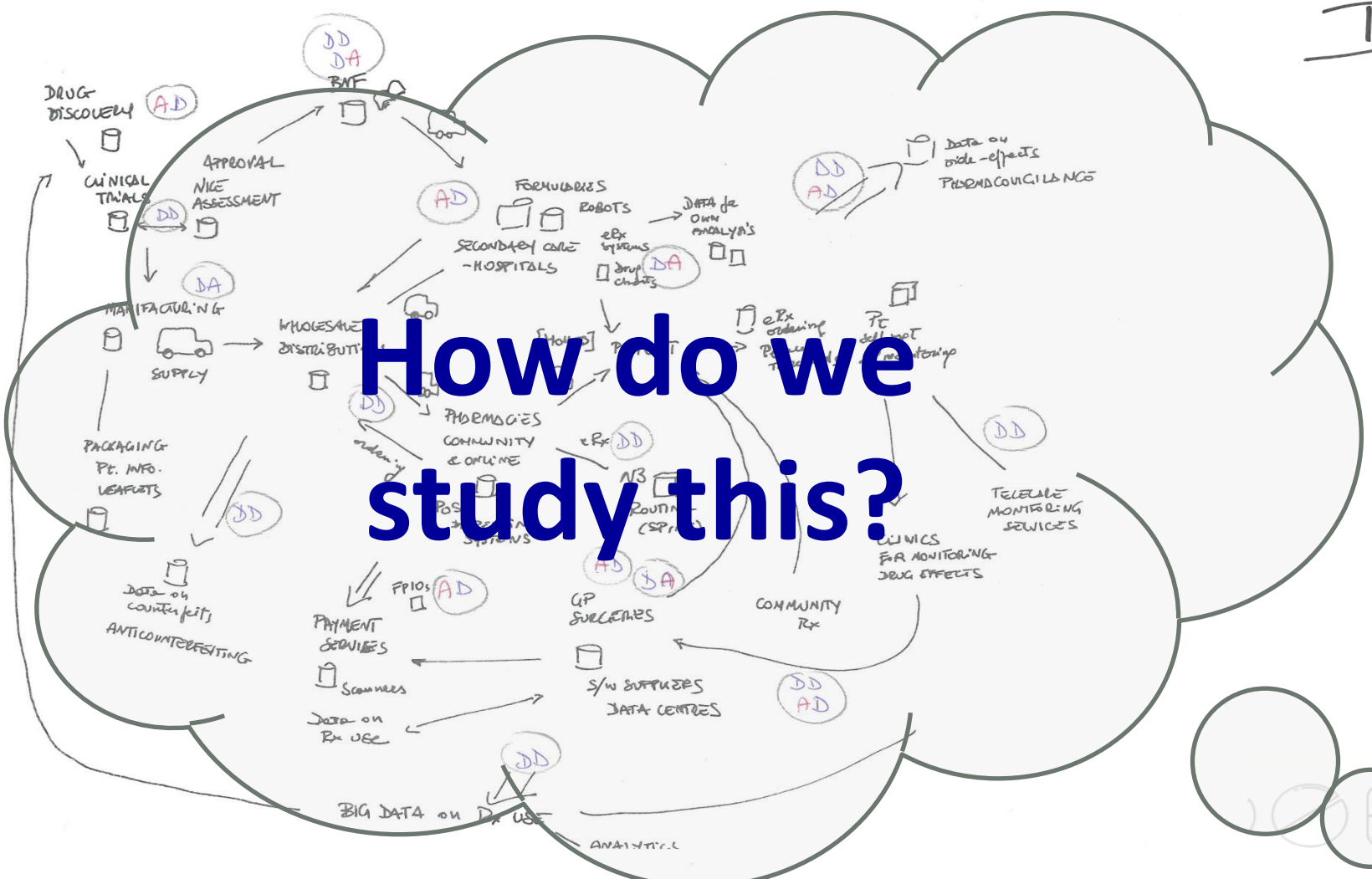
PAYMENT SERVICES
Scanners
Data on Rx use
AD
DA
GP SURGERIES
COMMUNITY Rx
S/W SUPPLIERS DATA CENTRES
DD AD
DD
BIG DATA on Rx USE
ANALYTICS

Conceptual foundations

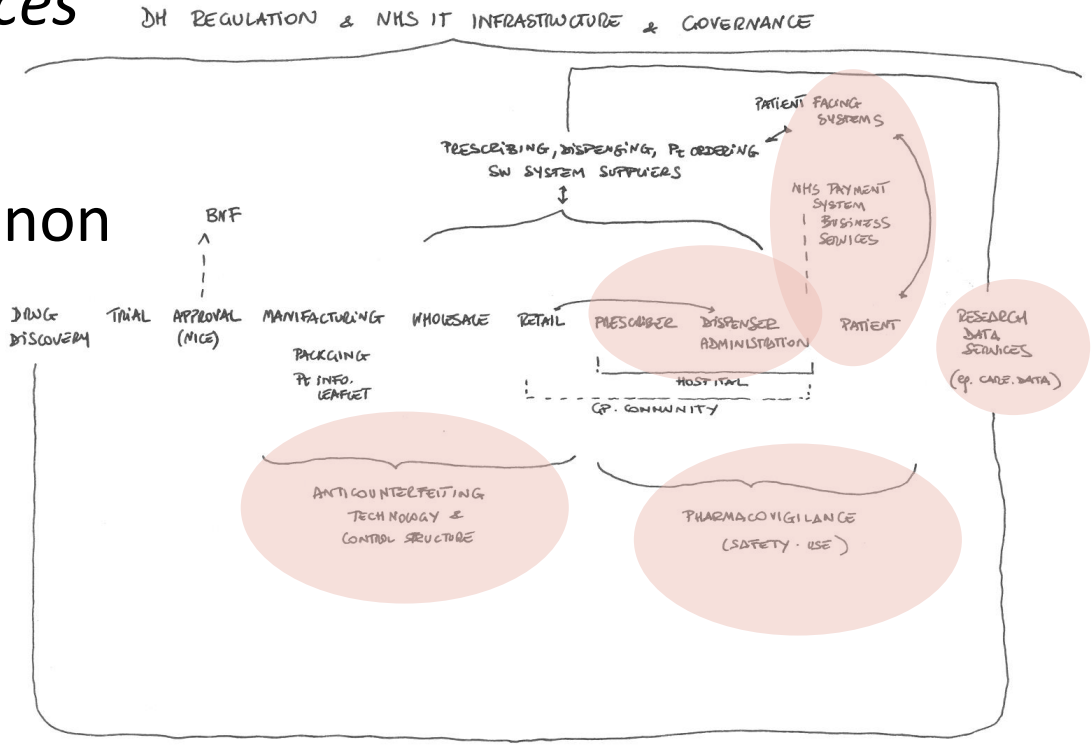
- *Digitization*: information that moves from analog to digital form (data) or when new digital data sources become available
- *Datafication*: the process of accumulation of these data and their multiple repurposing (as in, but not restricted to, Big Data); volume, velocity, variety.
- *Digitalization*: the wider sociotechnical changing associated to both (the subsequent reconfigurations of the socio-technical context of production and consumption of the associated products and services) – *a socio-digital reconfiguring?*
- *Agency migration:* the changing in how agency is (re)distributed as digitalisation occurs



How do we study this?

Study design: follow-the-drug in a multi-episode study

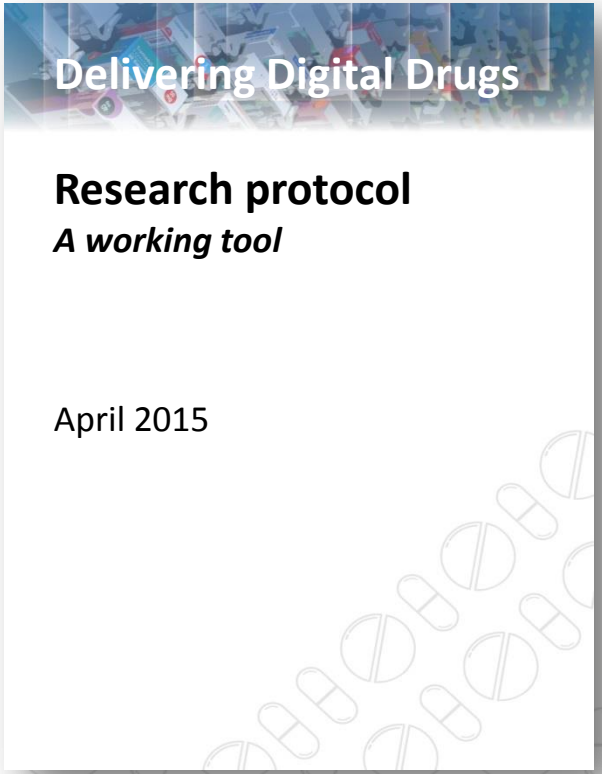
- A focus on *value, practices* and *business models*
- *5 Episodes*
  studies of the phenomenon of digitalisation of medicines
- *3 Exemplars*
  chosen drugs followed across the five studies (tracer approach)



Why Episodes?

- to reflect that drugs become digital incrementally and cumulatively through multiple transitions occurring in different places and times
- resonates with the temporal/historical nature of processes of digitalisation
- reminds us that studies of change (before-after studies) are but snapshots in a longer timeframe – a longer becoming
- to distinguish our study design from the more traditional case study research (Yin 2003)

Research Protocol



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Research Protocol

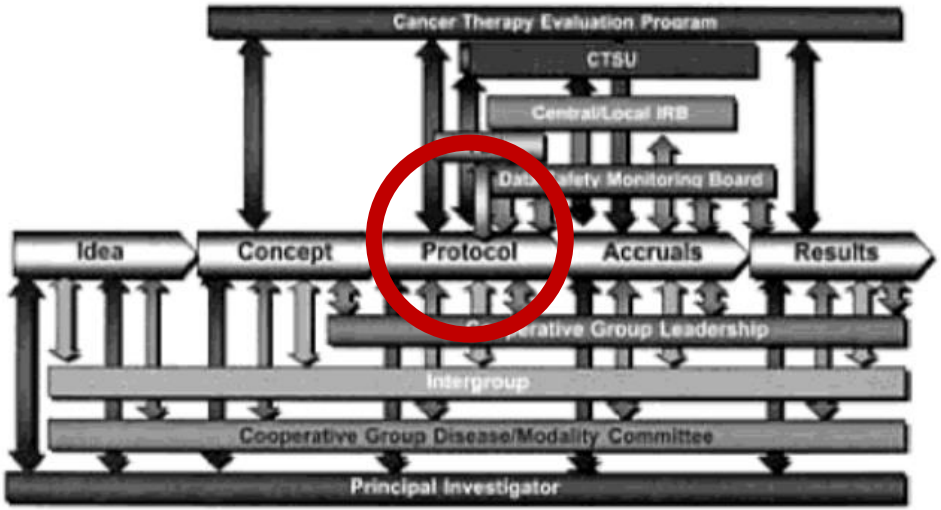

FIGURE 1.8. The front cover illustration of a cancer clinical trials publication, showing the central place occupied by the protocol. Reprinted from S. P. L. Leong, *Cancer Clinical Trials: Proactive Strategies* (New York: Springer, 2007), with kind permission of Springer Science+Business Media, and the Coalition of Cancer Cooperative Groups © 2002.

The term *protocol* originated in Medieval Latin where it referred to the first (proto) paper sheet glued (kolla) to the top of the minutes of public transactions and that outlined the contents of the resulting volume. As chronicled in the *OED*, the semantic field of the term has since undergone considerable extension, leading to the present-day scientific and clinical meanings that include the list of the successive steps of an experiment, the outline of a planned examination, or the agreed-upon schedule of chemotherapeutic drugs and dosages. The term thus has multiple meanings referring simultaneously to a legal authority, since its content is binding on the participating parties; a convention, for it is the result of a transaction between participants; a public, because as a communal document it is open to inspection by interested individuals or, at least, overseeing agencies and organizations; a prescription, since it dictates both the activities that have to be undertaken by participants and how they should be performed; and, finally, a description, insofar as it acts as a record of what has been done (see also Lynch, 2002).

Keating, P. and A. Cambrosio (2012) Cancer on trial: oncology as a new style of practice, University of Chicago Press. P25-26

What’s next? Maps and mapping

Maps and mapping

Rose, N. (2007). The politics of life itself: Biomedicine, power, and subjectivity in the twenty-first century, Princeton University Press

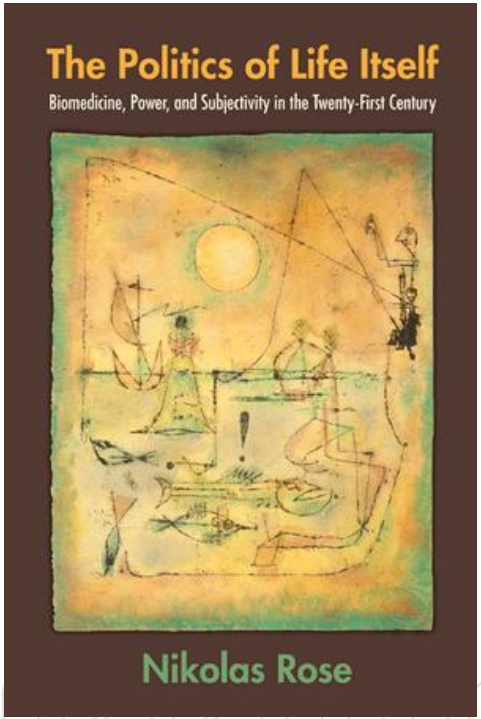

Table of Contents:

Maps and mapping

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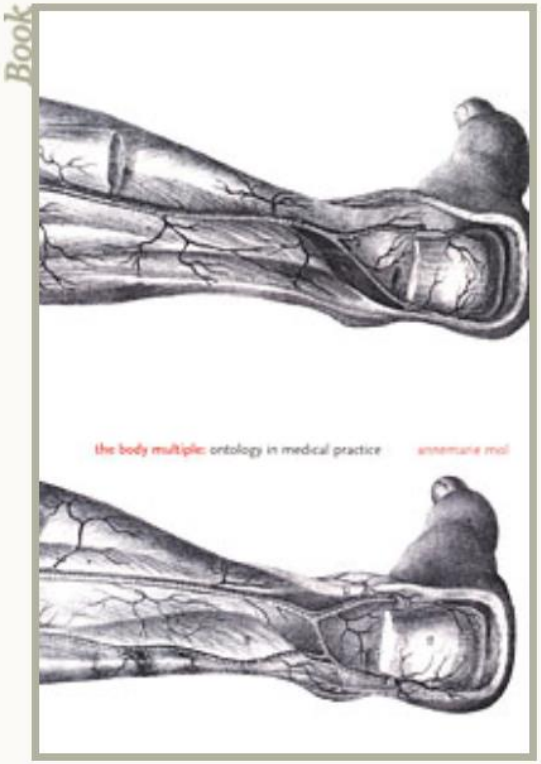

DETAILS | TABLE OF CONTENTS | AWARDS | EI

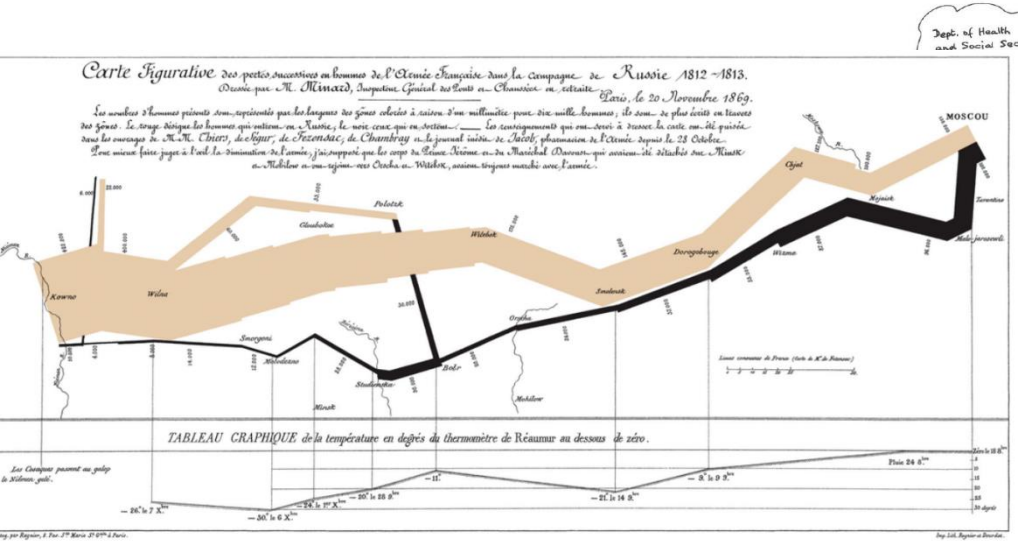
Carte Figurative des pertes successives en hommes de l'Armée Française dans la Campagne de Russie 1812-1813.
Dressée par M. Minard, Inspecteur Général des Ponts et Chaussées en retraite. Paris, le 20 Novembre 1869.
MOSCOU
Kowno
Wilna
Smorgoni
Minsk
Studienska
Mohilow
Polotsk
Glubokoe
Witebsk
Orscha
Dorogobouge
Smolensk
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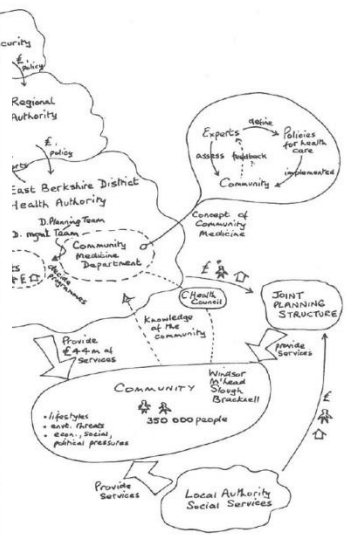
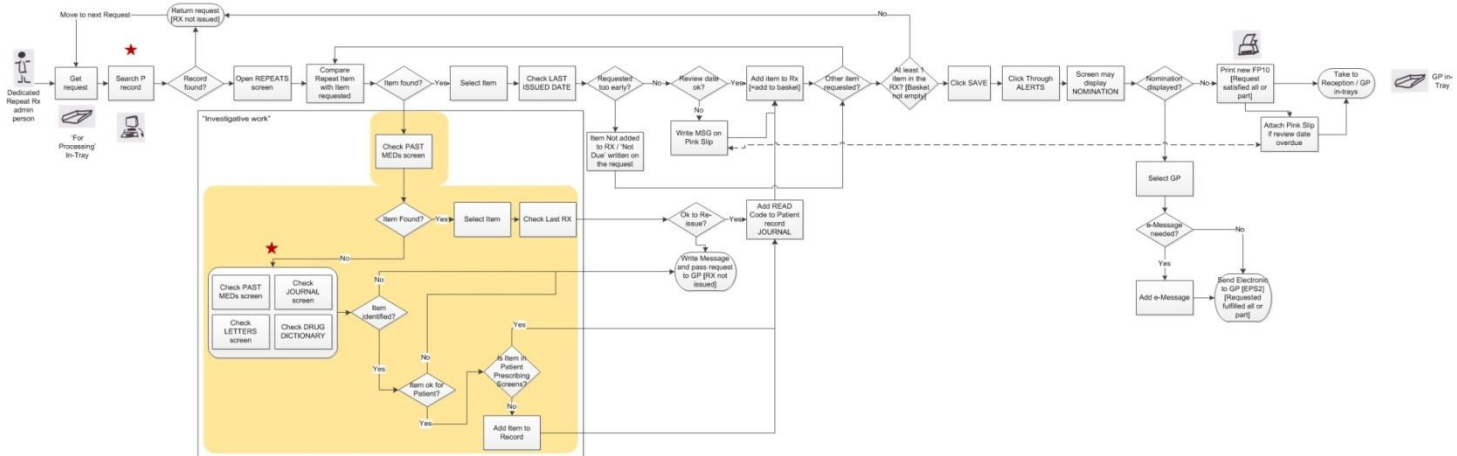
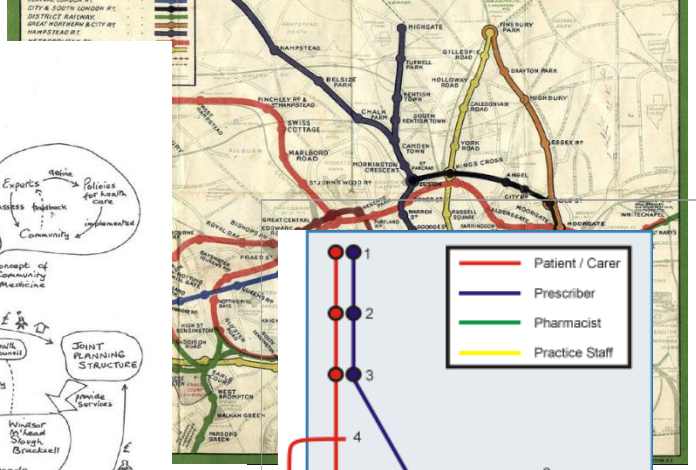
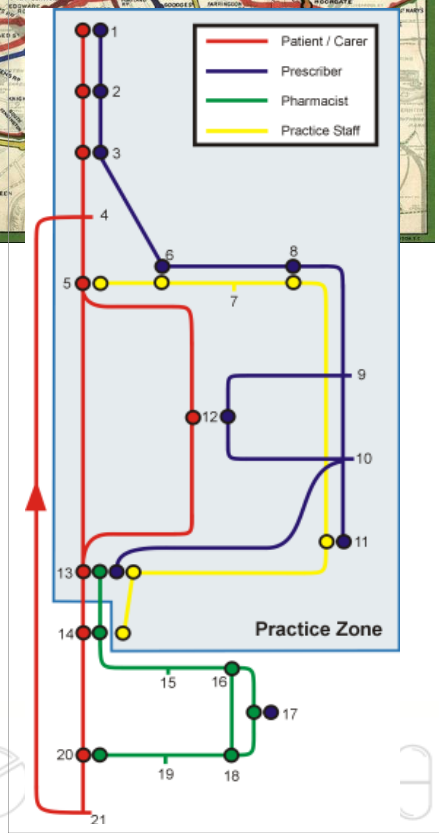
TABLEAU GRAPHIQUE de la température en degrés du thermomètre de Réaumur au dessous de zéro.


Dept. of Health and Social Security
Regional Authority
East Berkshire District Health Authority
Community Medicine Department
Concept of Community Medicine
Experts
Policies for health care
Community
Health Council
JOINT PLANNING STRUCTURE
Knowledge of the community
Provide Range of Services
Provide Services
COMMUNITY
Windsor Slough Bracknell
350 000 people
Provide Services
Local Authority Social Services


Move to next Request
Return request (RX not issued)
Dedicated Repeat Rx admin person
Get request
Search P record
Record found?
Open REPEATS screen
Compare Repeat Item with Item requested
Item found?
Select Item
Check LAST ISSUED DATE
Requested too early?
Review date ok?
Add Item to Rx Paddl to basket
Other item requested?
At least 1 item in the RX? [Basket not empty]
Click SAVE
Click Through ALERTS
Screen may display NOMINATION
Nomination displayed?
Print new FP10 [Request satisfied all or part]
Take to Reception / GP in-trays
GP in-Tray
'For Processing' In-Tray
Item Not added to RX / 'Not Due' written on the request
Write MSG on Pink Slip
Attach Pink Slip if review date overdue
Select GP
e-Message needed?
Add e-Message
Send Electronic to GP [EPS2] [Requested fulfilled all or part]
"Investigative work"
Check PAST MEDs screen
Item Found?
Select Item
Check Last RX
Ok to Re-issue?
Add READ Code to Patient record JOURNAL
Write Message and pass request to GP [RX not issued]
Check PAST MEDs screen
Check JOURNAL screen
Check LETTERS screen
Check DRUG DICTIONARY
Item identified?
Item ok for Patient?
Is Item in Patient Prescribing Screens?
Add Item to Record




Patient / Carer
Prescriber
Pharmacist
Practice Staff
Practice Zone
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21

Maps and mapping

"… facilitate the management and navigation through major public policy issues. These maps have benefits for policy analysts and decision-makers similar to those of geographic maps.
They provide patterned abstractions of policy landscapes that permit the decision-makers and their advisors to consider which roads to take within the wider policy context.
…".

Horn, R. (2001). Knowledge Mapping for Complex Social Messes. http://www.stanford.edu/~rhorn/SpchPackard.html.

Conclusion

- Next steps: access to sites, research in the field…
- Analysis – mapping and modelling …

Conclusions

- The process of developing the protocol : collaborative, informative and generative
- Asking questions to ourselves, provoked clarification of concepts
- Inspired writing and contributed to the LSE Research Festival poster

LSE RESEARCH FESTIVAL 2015

LSE Research Festival Exhibition

21 May 2015, 5.30-8.30pm

Lower ground floor, New Academic Building, LSE

Research Councils UK
Digital Economy
Transforming Business and Society

Following Digital Drugs

digital-drugs.org

Digital Drugs: noun, pl.,

drugs that are dependent on and substantially constituted by multiple digital representations and connections, and whose use and effectiveness is strongly mediated through digital means [1]

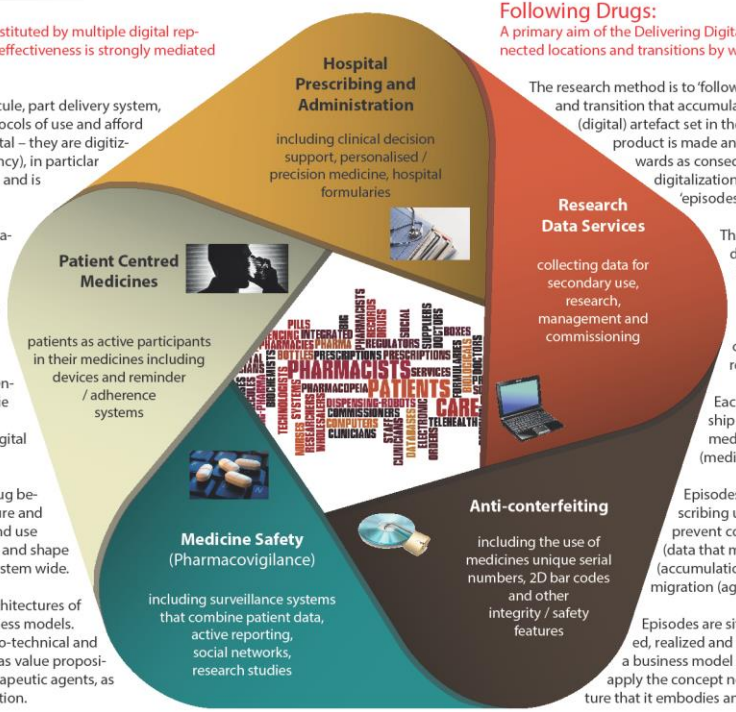
Medicines and Drugs are hybrids, part active molecule, part delivery system, part packaging and instructions, and embody protocols of use and afford work practices. They are also becoming in part digital – they are digitizing [2]. Their agency as artefacts (their material agency), in particlar their therapeutic potential, draws on digitised data and is applied through digitalised protocols.

From the supply chain, through clinical work and patients' bodies, to post-use data repositories and in structures of regulation, to follow a drug is to tell a story of material artefacts (devices, objects) and of chemical actions in biological milieu. But it is also a story of digital materiality and digital agency.

As a hybrid digital artefact a drug is constituted within, and an expression of, multiple digital reresentations and inter-connections. From the in-silico science of drug discovery, and testing procedures of randomised control trials, a drug is embodied as digital data.

And the digital sedimentations continue once a drug becomes a licensed product and moves to manufacture and then use. The people and groups who work with and use drugs (e.g. of us) are drawn in to the digit al sphere and shape new practices of medicines use, individually and system wide.

In this way digitalization implies new and novel architectures of value creation, realization and capture – new business models. These are expressed in reconfigurations of the socio-technical and economic context of medicines within healthcare; as value propositions, as products and increasingly services, as therapeutic agents, as the locus of innovation and as new forms of regulation.



Following Drugs:

A primary aim of the Delivering Digital Drugs project is to reveal the multiple and interconnected locations and transitions by which drugs become digital.

The research method is to 'follow the drug' and thereby map processes of digitalization and transition that accumulate a drug's digital materiality. Our interest is the drug as (digital) artefact set in the context of its use. We start from the factory where a product is made and follow it into the clinic, into and out of bodies, and on wards as consequence or outcome. As we follow a drug we see digitalization occurring in different settings – what we term 'episodes of digitalization'.

The word episode is chosen to reflect that drugs become digital cumulatively through multiple transitions occur ring in different places and times.

The 5 episodes under study are: anti counterfeiting; hospital prescribing and administration; patient centred medicine; drug safety (pharmacovigilance) and research data service (big data).

Each episode reflects a new entanglement in the relationship between material and virtual aspects and between medicinal product/artefact (drug) and medicinal practice (medicine).

Episodes of digitalization, for example a hospital doctor pre scribing using a computer, or a secure bar code being read to prevent counterfeiting, can be described in terms of: digitization (data that moves from analog to digital form), datafication (accumulation of data and its multiple repurposing), and agency migration (agency moving to the digital).

Episodes are situations in which a drug's therapeutic value is generated, realized and captured through digital means. We use the concept of a business model as a way of expressing a value architecture but we apply the concept not to the firm, but to the drug and to the value architecture that it embodies and which is significantly influenced by digitalization.

Thus we seek the healthcare logic of a specific practice, the value proposition it makes and to whom and the mobilization of resources and establishment of processes that it requires [3].

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This poster was prepared by:
Jane Dickson, Tony Cornford, Ralph Hibberd, Ela Klecun and Will Venters from LSE and Valentina Lichtner from Leeds University

LSE The London School of Economics and Political Science
University of Leeds
Brunel University London
UCL
The Health Foundation Inspiring Improvement

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[3] Christensen, C.M. Grossman, J.H. and Hwang, J (2009) The Innovator's Prescription: A Disruptive Solution for Health Care. McGraw Hill, New York

Conclusions

- How do we understand digitalisation?
- How do we study it?

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