

Can Blockchain Technology Help Regulatory Science? Claudia Pagliari BSc PhD FRCPE Director Global eHealth Programme University of Edinburgh @EeHRN

## Outline



- What is Blockchain?
- What are the big promises?
- How can it help the food sector and society?
- What are the risks, challenges & uncertainties?





### So, what is Blockchain?

- A **digital ledger**, distributed between members of a community and their computers, which records the history of **transactions** and enables transactions to take place securely
- Participants need a cryptic key to record a transaction. The record must then be encrypted via an algorithm and shared with everyone's computers for validation, before being stored on the blockchain
- When a record is updated, information from the previous record and the new one are combined to produce a new 'hash', creating a co-dependent chain of records
- If someone tries to change a record the algorithm will spot the difference. Since everyone has a copy of the 'true' record, this can substituted for the doctored one
- Different types of blockchains some can record more information
  (e.g. images for copyright) or enable 'smart contracts'





### What's so great about it?

" Simply put, the blockchain is a machine for creating trust.



- Transactions recorded on the blockchain are **immutable**
- Verification devolved to computers/algorithms => 'trustless'
- Information is secure and verifiable
- Records are transparent (everyone has a copy) but anonymous (they don't know what it means)
- Accountable because changes are visible to everyone and historical records and changes are traceable
- May allow peer-to-peer transactions without institutional middle-men like banks, lawyers and governments
- Can prevent identity theft, as IDs are encrypted
- May be linked to **devices (IoT**) or **biometrics**
- Automates processes necessary for verification
  = Faster administration & lower costs

## Public vs Private Blockchains



- Public blockchains, like Bitcoin, are fully decentralised, disintermediated, can be joined by anyone and are anonymous
- Private (corporate) blockchains are restricted to known members of a permissioned network
- 'Blockchain as a service' = cloud-based platforms which businesses or communities can rent to build or host blockchain apps





### Gartner Hype Cycle for Emerging Technologies, 2017

- Still few actual use cases in biomedical research or the food sector
- Many innovations 'in progress'
- More caution since cryptocurrency hacks

### Challenges for biomedical research

*Efficient Management* – Smooth trial conduct, reproducibility, effective data sharing, patient enrolment etc.

*Effective Governance* – Transparency, Informed Consent, Accountability, Harm (physical, psychological; current vs future). Integrity of purpose. Manipulation, Incentives, Crime



Similar issues for the food sector, although medicine is more concerned with patient confidentiality

## Good Governance



Usually reserved for conversations about global development, the term Good Governance is useful in this context

Key features:

Consumer Participation, Rule of Law/Regulations, Transparency, Responsiveness, Consensus Orientation, Equity, Effectiveness and Efficiency, Accountability, Strategic Vision

UNDP (1997) *Governance for Sustainable Human Development*. United Nations Development Programme

Electronic supplementary material: The online version of this article contains supplementary material



- > Ethics
- > Integrity
- > Processes

Digital technology for health sector governance in low and middle income countries: a scoping review

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<sup>1</sup> Cambridge Judge Business School, Cambridge, UK <sup>8</sup> Medic Mobile, San Francisco, CA, USA <sup>8</sup> Ediriburgh Global Health Academy & Unher Institute of Population Health Sciences and Informatics. Background Poor governance impedes the provision of equitable a cost-effective health care in many low- and middle-income countr (LMICs). Although systemic problems such as corruption and in ficiency have been characterized as intractable, "good governanc interventions that promote transparency, accountability and pub participation have vielded encouraging results. Mobile phones a

## Strawberries in December









### "Backbone of Supply Chain Digitisation"

In supply chain applications, blockchain has already taken off its Sex Pistols T-shirt and started wearing a cardigan CP Quoted in Chemistry World, Aug 2018



### Counterfeiting

ot, so that the

Adds information about the product to the database Customer Customer

Reads a OR code or Digmus NFC tag to verify if the product is genuine or counterfeit

Manufacturer

Fake medicines are rife in LMIC. Fake malaria and tuberculosis drugs alone cause c 700,000 deaths p/a

**Sproxil** - Scratch code reveals a QR or SMS which can be sent by SMS or App, to a call centre or checked on the web. Now blockchain backed

**Blockverify** targets pharmaceuticals, luxury items, diamonds & electronics. Every product has its private key stored in blockchain. With a track and trace number it is possible to trace change of ownership

"Adding scannable blockchain-

connected tags, tamperproof seals or imprints to products is one of the most convincing use cases of distributed ledger technology in fighting counterfeits" WIPO, 2018



### Substitution





Fifth of meat tests reveal unspecified DNA bbc.co.uk

## Mis-labelling



### Country of origin. Organic. Wrong Species.

### Food fingerprinting

"As the fruit grows, it's picking up a unique signature at the isotopic level. These **chemical barcodes** can help us prove that the product comes from a specific location. If that orange travels to a factory in another state, it is logged in the system and its place of origin recorded. If it's made into marmalade, that's also logged in the system. If we picked that marmalade up at the supermarket and tested it, we could still confirm the fruit's place of origin ... If the test failed, we could easily look back through the chain to see where things went awry" (Not yet in place)

Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO) Sept 4th, 2018 on the use of blockchain in food counterfeiting

## Preventing Food-Borne Illness



#### CIO JOURNAL

### Walmart-Led Blockchain Effort Seeks Farm-to-**Grocery-Aisle View of Food Supply Chain**

The grocery giant, together with Nestlé, Dole and others, wants to set new industry standards on food tracking

By Kim S. Nash Jun 25, 2018 1:05 pm ET **9** 5 COMMENTS



A Food Trust trace of a shipment of strawberries in early December 2017 shows that eled from two distributors, in Clarksville, Ark., and Ochelata, Okla., to five Walmart stores. PHOTO: KIM S. NASH / THE WALL STREET JOURNAL

### FINANCIAL TIMES

### From farm to plate, blockchain dishes up simple food tracking

Technology promises to make provenance of goods and supply hiccups easier to pinpoint Louise Lucas JUNE 6, 2018



feat safe: Walmart is using blockchain to trace the origin of pork in China @ Bloomberg

### **Blockchain Gains Traction in the Food Supply Chain** Forbes



Steve Banker Contributor ① cover logistics and supply chain management.



After implementing blockchain Walmart went from needing 6 days to 2 seconds for tracing a contaminated product from shelf to source

## Protecting reputations







## Compliance, safety & IoT

Modium.io uses **Internet of Things** sensors to measure the **temperature** of medicines during transportation from source to retailer. Data is automatically sent to the blockchain creating immutable and transparent records

This **automatically audits compliance** with the "Good Distribution Practice of medicinal products for human use" (GDP 2013/C 343/01), which requires proof that shipped medicines have not been exposed to conditions that may compromise their quality



## Engaging the consumer



"The way we produce food is sometimes hidden from the consumer. Without real transparency ...we will be producing our own scandals"

Bernhard Url, Opening this meeting

BitCive

**Give**Track



## Regulatory Innovation

### Automating regulation?

- Digitisation ->
- Automation ->
- Codification
- Smart contracts



**Bernhard Url** @BUrl EFSA

Looking at the speed of change outside our domain of #FoodSafety I ask myself: how can we keep pace with #Innovation & keep our methodologies up to date? How can we keep a small organisation like EFSA agile enough to be able to absorb the complexity of future challenges? #EFSA2018



### Blockchain Technology as a Regulatory Technology From Code is Law to Law is Code

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### The Challenge of Incremental Innovation



### thebmj Research - Education - News & Views - Campaigns -

### Regulating incremental innovation in medical devices

*BMJ* 2014 ; 349 doi: https://doi.org/10.1136/bmj.g5303 (Published 09 September 2014) Cite this as: *BMJ* 2014;349:g5303

Unlike drugs, medical devices can evolve rapidly in basic design or technology. This is largely unregulated (by FDA)

'The competitive position of the European food and drink industry' report states that most innovations can be characterised as 'incremental innovations or imitations" (European Commission 2016)



Copyright & Intellectual Property



- Copyright, Intellectual Property, Knowledge Capital
- Could blockchain enable more agile and adaptive IP/copyrighting?
- Risk of complexifying copyright beyond human ability to understand?
- New report on Blockchain from the World Intellectual Property Organisation 2018
- EU Commission plans a blockchain observatory. US Congress recently created a Congressional Blockchain Caucus. Global standards for self-executing contracts are being discussed by various organizations

## Scientific currency?

- Unpublished negative research
- Blockchain solutions exist
- •Could aid open science for better decision making
- Potential provenance tool for academics to record their micro contributions

### Blockchain moves to science

Proponents say the system behind Bitcoin could lend security measures to the scientific process.

#### BY ANDY EXTANCE

The much-hyped technology behind Bitcoin, known as blockchain, has intoxicated investors around the world and is now making tentative inroads into science, spurred by broad promises that it can transform key elements of the research enterprise. Supporters say that it could enhance reproducibility and the peer-review process by creating incorruptible data trails and securely recording publication decisions. But some also argue that the buzz surrounding blockchain often exceeds reality, and that incorporating the approach into science could prove expensive and introduce ethical problems.

A few collaborations, such as Scienceroot and Pluto, are already developing pilot projects to use blockchain for science. Scienceroot aims to raise US\$20 million, which will help to now both scene regioneer and unknew athlen its



Mining for bitcoins creates a large computational demand.



### Security & Secrecy



Hackers are stealing food science data. With blockchain it's distributed & connections are protected

Securing the data may lead to cost-efficiencies e.g. automated due-diligence

However future decryption technologies (e.g. quantum) may threaten information encrypted and stored on public blockchains

"The agri-food business is filled with secrets, so blockchain technology could be problematic for many companies"

In high accountability sectors, balancing confidentiality with transparency is a challenge

## Challenges: Maintaining Data Integrity



### How 'immutable' are the data?

Need to understand how human error might play a role and how to deal with this

What happens if erroneous data ends up in an immutable BC?



## Oversight, Trust, Power



Who is really 'in charge', is it always the community or is there a core party?

Government vs corporate values

Companies like Walmart, have more power and influence over other companies within the same supply chain

Private vs public blockchains



Businesses use blockchain to take on trustlessness

### Territories

Multiple blockchains and BC types

## Mega-corporate local or community-owned

Laws & regulations vary across regions







### Environment



New forms of energy consumption

More of an issue for cryptocurrency requiring computer-intensive 'mining'

The energy sector itself is attempting to use Blockchain to <u>decrease</u> consumption

- Carbon credits as a social machine

Private BC are less energy-hungry

Could reduce waste in the supply chain, potentially -> carbon neutral

### Privacy and Confidentiality



Zero knowledge protocols?

# Information on a public blockchain may, in fact, be hackable



### Conclusions & Conundrums



Potential benefits: Transparency, accountability, efficiency, safety

Business case still unproven, aside from supply chain logistics

Hack resilience not yet fully tested (bad actors)

Decentralised, democratic vision may be disrupted by powerful platform controllers

Private blockchains aren't fully anonymous

International blockchain governance is needed

But let's not give up the baby with the bath water!

### Thank you



Claudia Pagliari @EeHRN

