



# Maximizing the value of clinical trial data

A decade of data sharing, what have we learnt?

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Data Sharing  
from Past to  
Present – What  
have we learnt?



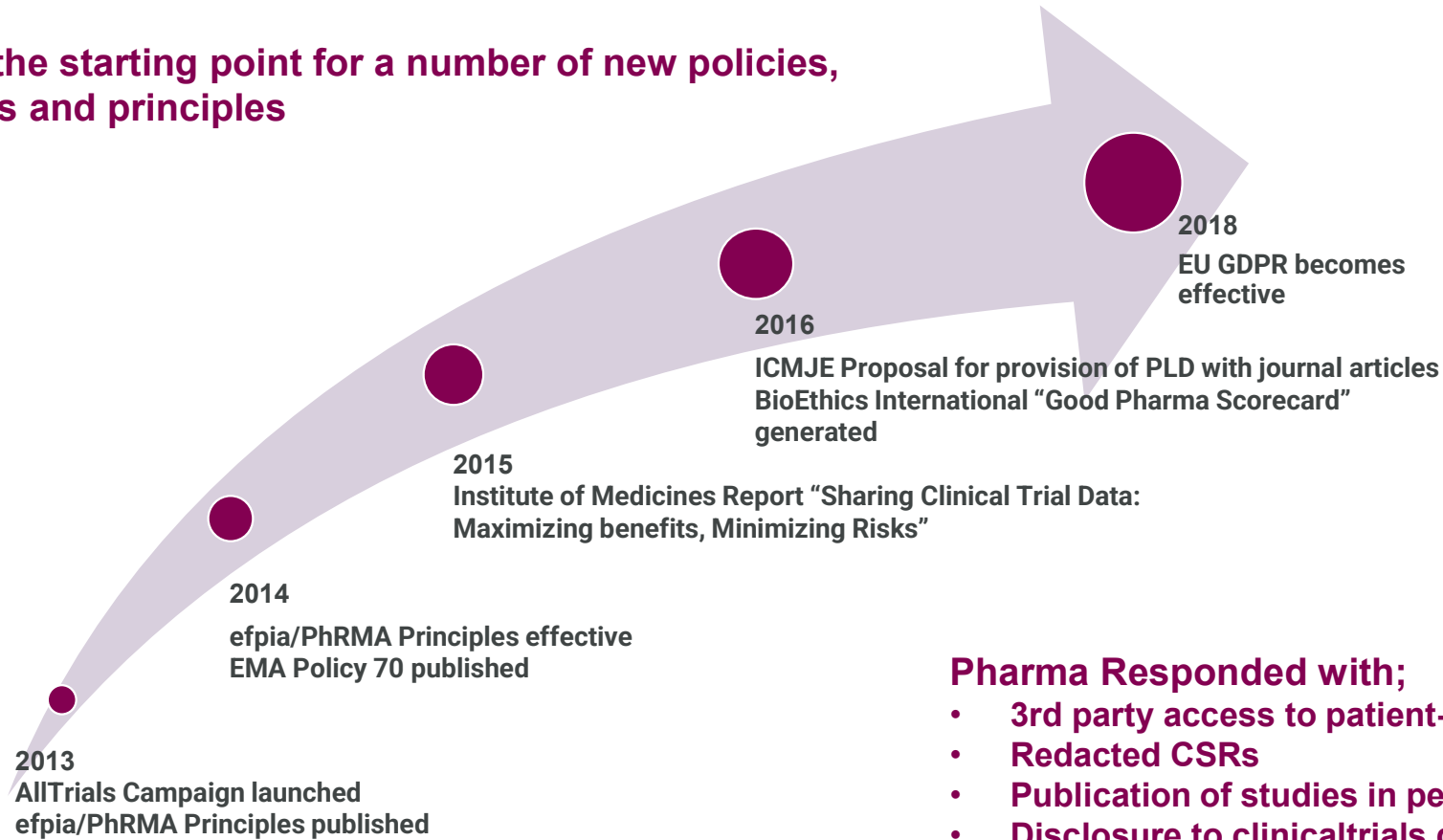
*Pharma Industry under increased  
scrutiny; calls for greater clinical trial transparency and release of  
patient level data*

**TRANSPARENCY = TRUST**



# Where have we got to in the Data Sharing Journey?

**2013 was the starting point for a number of new policies, regulations and principles**



## Data Sharing Platforms: Insights Shared?

	Yoda	Vivli	CSDR
<b>Active since</b>	2013/14	July 2018	Jan 2014
<b>No trials listed*</b>	Not clear from website	6600	3046
<b>No of data contributing organisations</b>	4	46	12
<b>No of publications to date</b>	103	176	132



# Companies are spending a lot of effort and resources to make data available and has value been generated?



EMA Clinical Data Portal



- **Tangible**

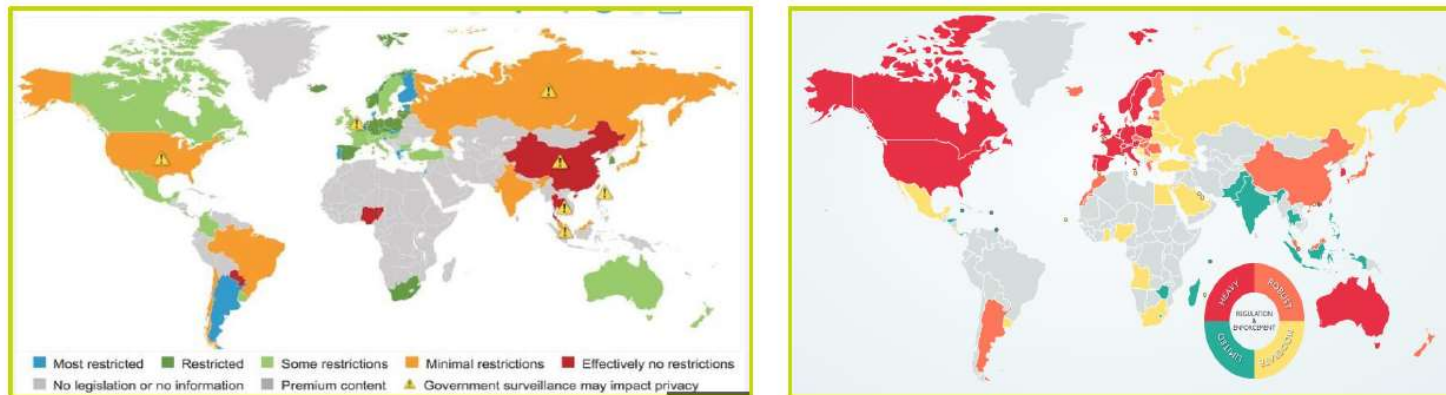
- Vivli Infor Data-reuse from data sharing platforms have led to publications, Tools, Design of Future Trials, Algorithms / code, Clinical Guidelines and Regulatory Submissions

- **Intangible**

- Organisational learnings & cross-functional collaboration to accelerate up e.g. COVID pandemic



# Today +100 countries have a privacy laws and the number keeps increasing



Two recent developments which represent further obstacle to being able to transfer personal data across borders

1

## Schrems ii

The law came into affect 27<sup>th</sup> Sep 2021 A recent EU court case and subsequent binding guidance issued by EU Privacy Regulators will have a significant impact on organisations that transfer personal data from the EU to the rest of the world.

2

## China CDBT

Provides the potential for substantial fines and other sanctions for non-compliance

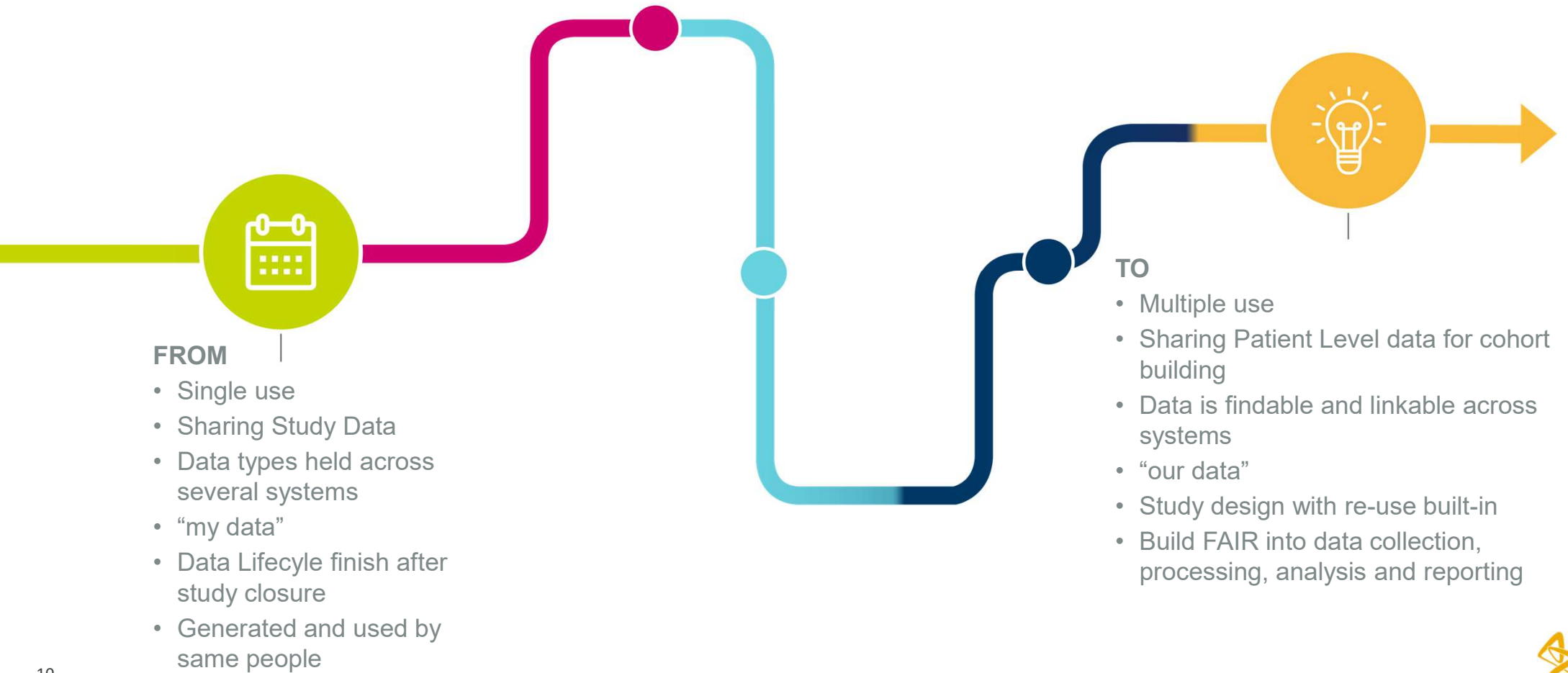




What might the  
Data Sharing  
future hold?



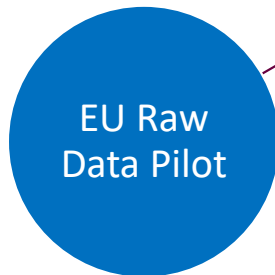
# What can we learn from past data sharing's to inform the future?



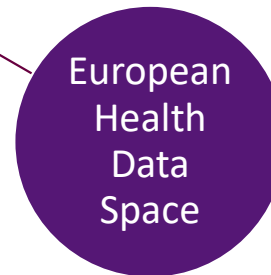
# Large Data Sharing Initiatives on the horizon!



Development of a framework which would allow the re-use and return of clinical trial data to study participants



The EMA has launched a pilot project to assess whether the analysis of 'Raw' patient level data from clinical trials by regulatory authorities improves the evaluation of marketing authorization.



The EHDS is aiming to set up an ecosystem of rules, infrastructure and governance framework enabling the use of health data for research

**COVID pandemic drove faster and more data sharing's which has inspired new way of thinking**



What  
opportunities are  
there for  
collaboration?

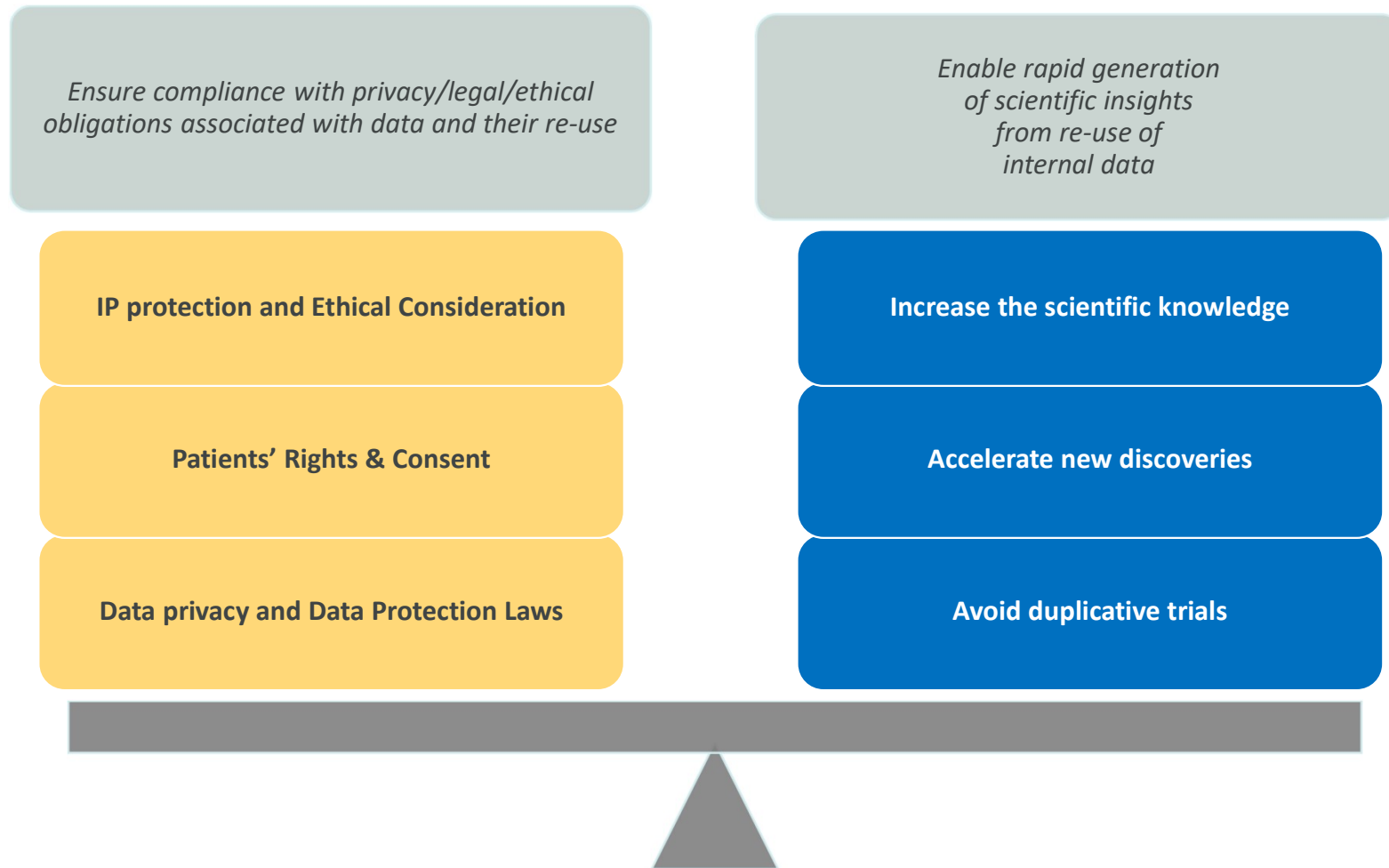


# Where Next? What opportunities are there for collaboration?

- Value of working together – the power of non-competitive problem solving!
- Opportunities for industry to solve data challenges such as;
  1. Better understand researchers wanting access to data and their priorities
  2. Increase interoperability of data and look at minimum requirements
  3. Build FAIR into data collection, processing, analysis and reporting
  4. Enable access to data beyond the “CSR” e.g. Images, Omics, Digital, device data
- Opportunities for broader independent research;
  1. Level playing field for all clinical trials, including Academic funded trial
  2. Avoid fragmentation with Data Sharing platforms
- Continued cross-stakeholder collaboration needed e.g. CRDSA, PhUSE, EFSPi/PSI, TransCelerate



# It's a balancing act! We need to promote safe and responsible information sharing and re-use



# How do we apply Data Protection to Data Lifecycle Management?

## 08. Compliance

- ✓ Privacy by design
- ✓ Data encryption applied
- ✓ Masking techniques used
- ✓ Exceptions and deviations documented
- ✓ Data protection breaches reported

## 07. Disposal

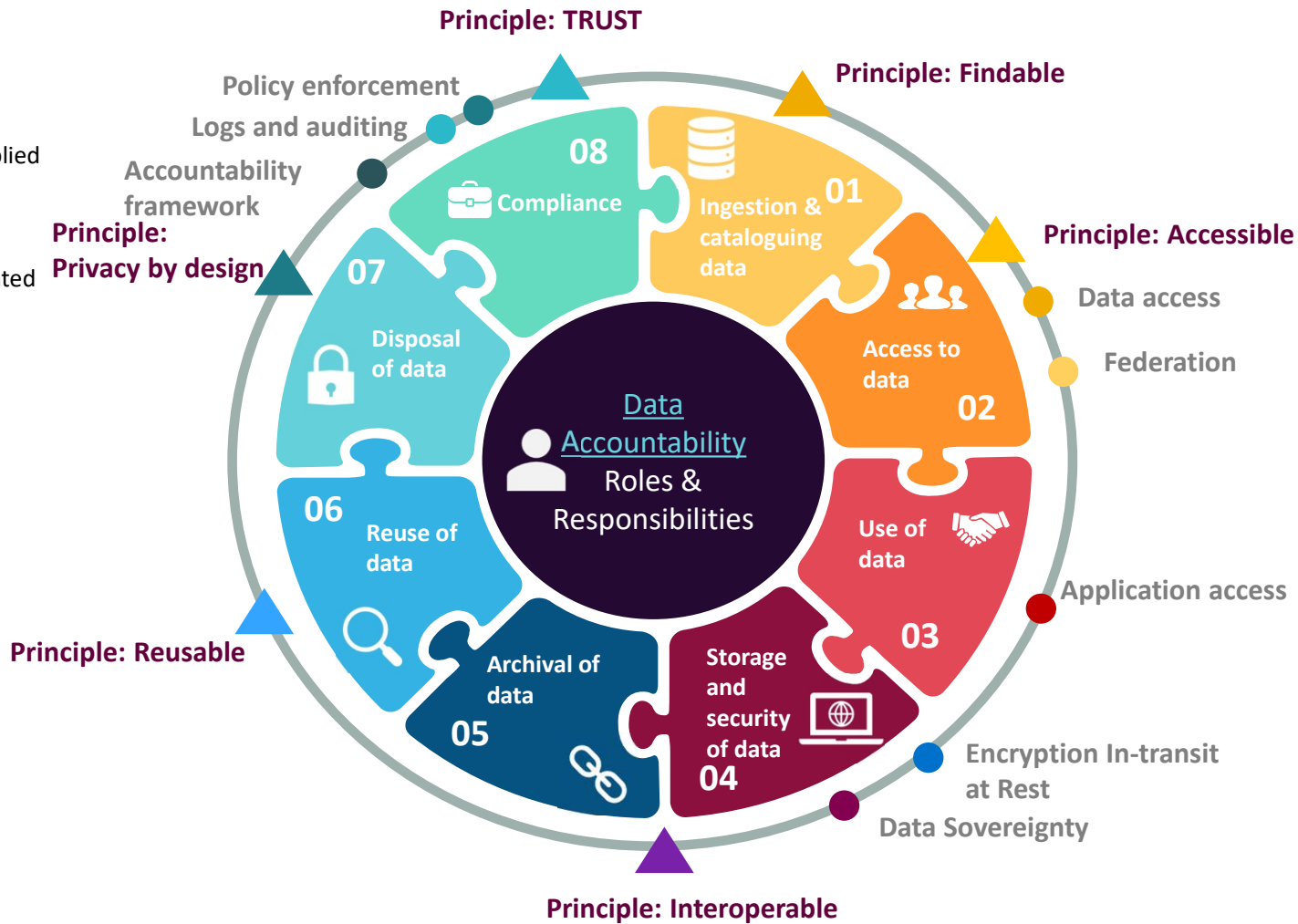
- ✓ Storage limitation

## 06. Reuse

- ✓ Legal, ethical basis
- ✓ Scientific merit
- ✓ Business sensitivity
- ✓ Contractual restrictions and data ownership

## 05. Archival

- ✓ Contractual obligations
- ✓ Data ownership
- ✓ Lineage



## 01. Ingestion & Cataloguing

- ✓ Accurate registration of assets
- ✓ Minimum metadata model applied
- ✓ Standard model for ingestion used
- ✓ Integrity and quality of processes

## 02. Access

- ✓ Policy to provide business rules
- ✓ Dataset selection according to attributes
- ✓ Purpose, users and time specified

## 03. Use

- ✓ Data location known and maintained
- ✓ Audit trail

## 04. Storage and security

- ✓ Recovery solution in place
- ✓ Error handling
- ✓ Transfers into, within and outside the enterprise



# What does this mean to statistics departments?

- All the data sharing work requires a new way of thinking when it comes to use of data and data –reuse
- There are aspects to consider on how much of the data sharing knowledge statisticians should have compared to support function?
- Are there opportunities for further Learning & Development?

**Break-out sessions to follow to explore key themes**





# Have aspects changed in Trust & Transparency?



- Metrics on commonly used data sharing platforms e.g. Vivli and the Good Pharma Scorecard show increased transparency
- Collectively working together will ensure that the data and time that all our trial subjects have given will benefit patients, society and the industry

**... The journey has started but there are still lots to be done!**





Thank You

