



Hey Data Scientist: Are You Following the Rules and Your Conscience?

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Disclaimer:

Although we are often asked about planning data submissions, we are not Regulatory Professionals. This presentation is based solely on our own experience. Data submission decisions are very complicated and require written FDA agreement.

In our regulated environment we have checklists, good practice training, SOPs, regulations, and even software meant to keep us on the straight and narrow.

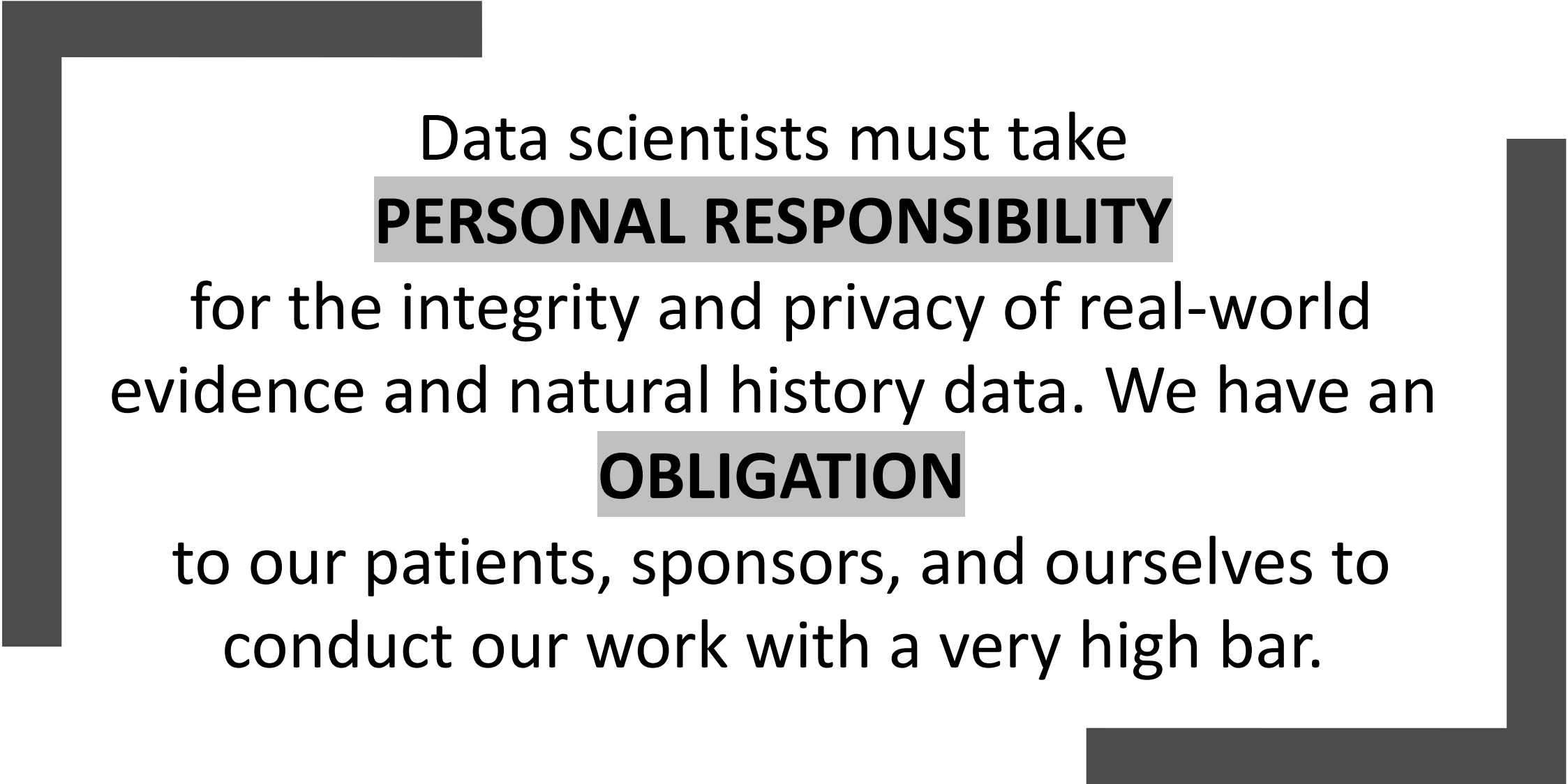
We are here to talk about something else...



con·science

- *noun*
 - an inner feeling or voice viewed as acting as a guide to the rightness or wrongness of one's behavior



A dark gray L-shaped frame surrounds the text. It consists of a vertical bar on the left and a horizontal bar at the top, meeting at a corner. Another vertical bar is on the right, and a horizontal bar is at the bottom, meeting at a corner.

Data scientists must take
PERSONAL RESPONSIBILITY

for the integrity and privacy of real-world
evidence and natural history data. We have an

OBLIGATION

to our patients, sponsors, and ourselves to
conduct our work with a very high bar.

How can we take a broader view of our work from a position of principle?

prin·ci·ple

noun

a rule or belief governing one's personal behavior





This is Charles...

He is a data scientist and wants to do the right thing.



Charles must take a broader view and ask himself important questions to ensure he is conducting his work according to his conscience.

The Broader View

As it relates to...

- Consent
- Chain of Custody
- Provenance
- Privacy
- Due Diligence

Definitions

 Oxford Dictionaries



NIST National Institute of
Standards and Technology
U.S. Department of Commerce



Consent

Permission granted in the knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with full knowledge of the possible risks and benefits.



Chain of Custody

A process that tracks the movement of evidence through its collection, safeguarding, and analysis lifecycle by documenting each person who handled the evidence, the date/time it was collected or transferred, and the purpose for the transfer.



Provenance

A record of ownership used as a guide to authenticity or quality.



Privacy

The laws, regulations, and protocols that help patients control who sees their sensitive medical information.



Due Diligence

The care that a reasonable person exercises to avoid harm to other persons or their property.

Consent

Permission granted in the knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with full knowledge of the possible risks and benefits.

- Is there evidence that the patient provided Informed Consent?
- Is the data element I am collecting covered by any known Informed Consent?
- Did who gave us this data have a right to share it with us?
- Do we have a right to have and disseminate this data?

Real World Evidence (RWE) poses challenges surrounding Informed Consent (IC)

Sources for RWE that may make Charles scratch his head regarding IC:

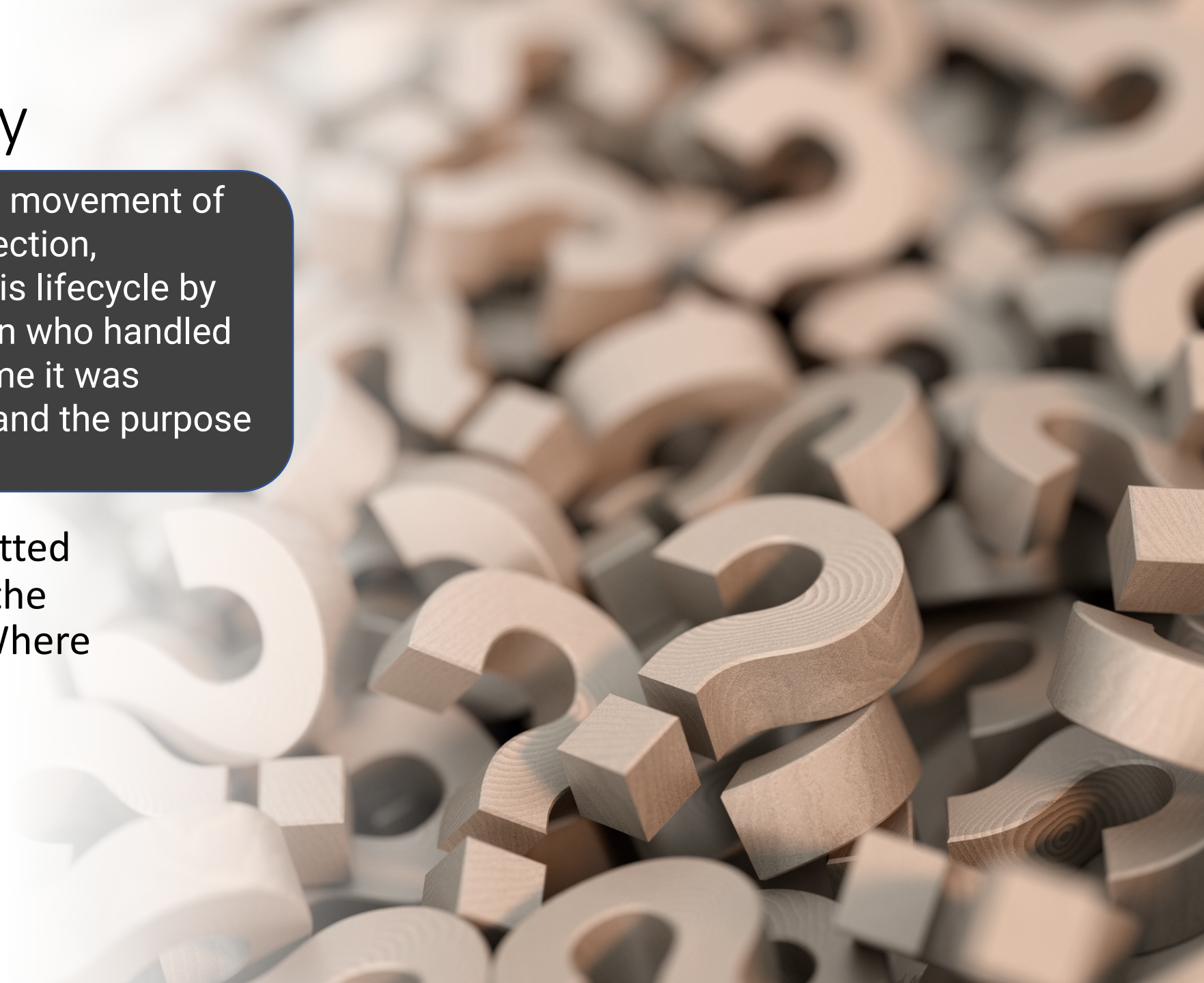
- ☐ Medical charts
- ☐ Published medical literature
- ☐ Specialty clinics providing historical data
- ☐ Emails from investigators
- ☐ Discussions with authors at conferences



Chain of Custody

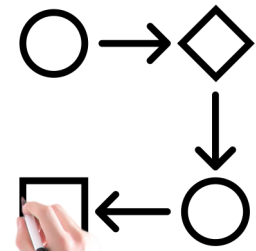
A process that tracks the movement of evidence through its collection, safeguarding, and analysis lifecycle by documenting each person who handled the evidence, the date/time it was collected or transferred, and the purpose for the transfer.

- Was the data transmitted in a way to maintain the Who, What, When, Where and Why?



Charles must
be able to
recreate the
data's path
from collection
to analysis

- ✓ Data transfer agreements
- ✓ 21 CFR 11 compliant data storage
- ✓ Time stamps for files are maintained
- ✓ Data definitions and reviewer guides that adequately describe data traceability





Provenance

A record of ownership used as a guide to authenticity or quality.

- Is this data a true and final version that was used in the deliverable?
- Do we have the documentation to show how this data was made with quality?
- Is the data complete with minimized missing values for the specified analysis?

Charles double checked that the data is ready for health authority filing before he provided it to his regulatory department

- ✓ Timestamps
- ✓ File counts
- ✓ All required elements present
- ✓ QC and/or programming validation logs complete





Privacy

The laws, regulations, and protocols that help patients control who sees their sensitive medical information.

- Does our data and documentation maintain the privacy of the identity of our patients?
- Has appropriate redaction been completed?

Charles made
sure nobody
could identify
the patients
from the
records

Before storing records on his
systems, he:

- ✓ Blurred faces in patient
videos
- ✓ Blacked out identifying
information from medical
charts



Due Diligence

The care that a reasonable person exercises to avoid harm to other persons or their property.

- Have we compiled, documented, and analyzed data in a way that shows the care expected for a regulatory filing?



Charles maintained good records, so that he and his colleagues would be able to answer the hard questions during inspections or information requests

- ✓ Made notes to file for confusing or unusual data circumstances
- ✓ Made flow charts for data mapping that required decisions and dependencies
- ✓ Made a storyboard for complicated data collection scenarios
- ✓ Had a process for QC or review of data extraction, trained resources, and had sign-off upon completion



What should Charles do if he identifies an issue?



- ☐ Talk to project lead
- ☐ Review project communication plan and follow escalation plan
- ☐ Refer to regulatory guidance documents
- ☐ Talk to regulatory or quality
- ☐ Talk to your boss



Sometimes there is just a misunderstanding and with more information or explanation, the problem disappears.

Key Takeaways

1. Let's follow our conscience and principles in how we work.
2. Let our principles guide our clinical data practices.

 IrisStatisticalComputing



THANK
YOU!

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