**Introduction**

In response to public pressure for transparency, regulatory authorities begin requiring that clinical trial data be published. However, true data transparency also requires that reported data are accurate and are coming from the official source.

**Multiple Data Formats**

The problem is that data resides in a myriad of systems and formats (see figure 1). This makes it difficult to maintain data lineage through the clinical lifecycle. To keep track of a data element, it should be defined broadly for use across the lifecycle, but managed granularly by managing data about the data, the ‘metadata’.

**Metadata & Data Transparency**

Metadata enables data transparency in two ways:
- describing the data characteristics and formats, including clear information about data lineage and transformations throughout the lifecycle.
- describing when a data element was used and for which purpose, showing relationships from data for collection use (e.g. a protocol) through how it is used in analysis and reporting for a dossier.

**Spreadsheets are not the best tool**

Spreadsheets do not support things like change control, versioning, business rules, impact analysis or reuse of elements. This has to be done manually introducing human error as well as extra work. A metadata repository can serve as the single source of truth, enable review of all references and transformations, and link the data element to each specific use case for impact analysis.

**How metadata enables transparent data reuse**

Metadata Repository

- **Name:** PULSE
- **Label:** Pulse Rate
- **Type:** Num
- **Length:** 3
- **Domain:** VS
- **Visit:** Baseline, 1M, 3M, etc.
- **Table:** 2
- **Header:** PR

**Standards**

- Industry Defined Semantics
- CDISC PRM, CDASH, SDTM, ADaM standard
- Internal Data Collection/Reporting Standard

**Metadata Management**

A well-designed metadata repository will enable data transparency by:
- Creating, maintaining, governing and using metadata standards consistently
- Maximum reuse of existing artifacts and data assets
- Understanding the impact of changes on other people, processes and systems
- Knowing data exchanged with others is being used or interpreted correctly