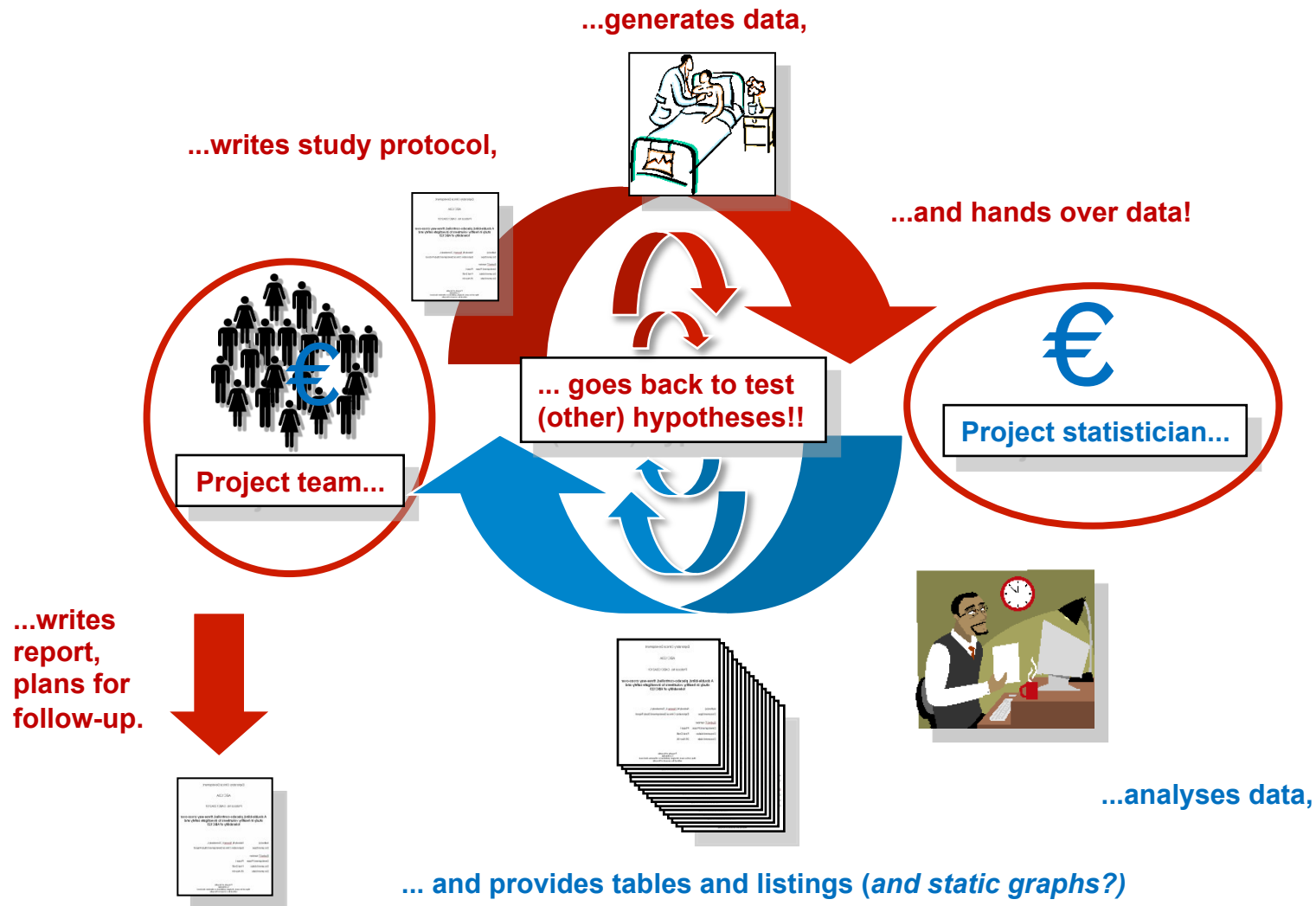


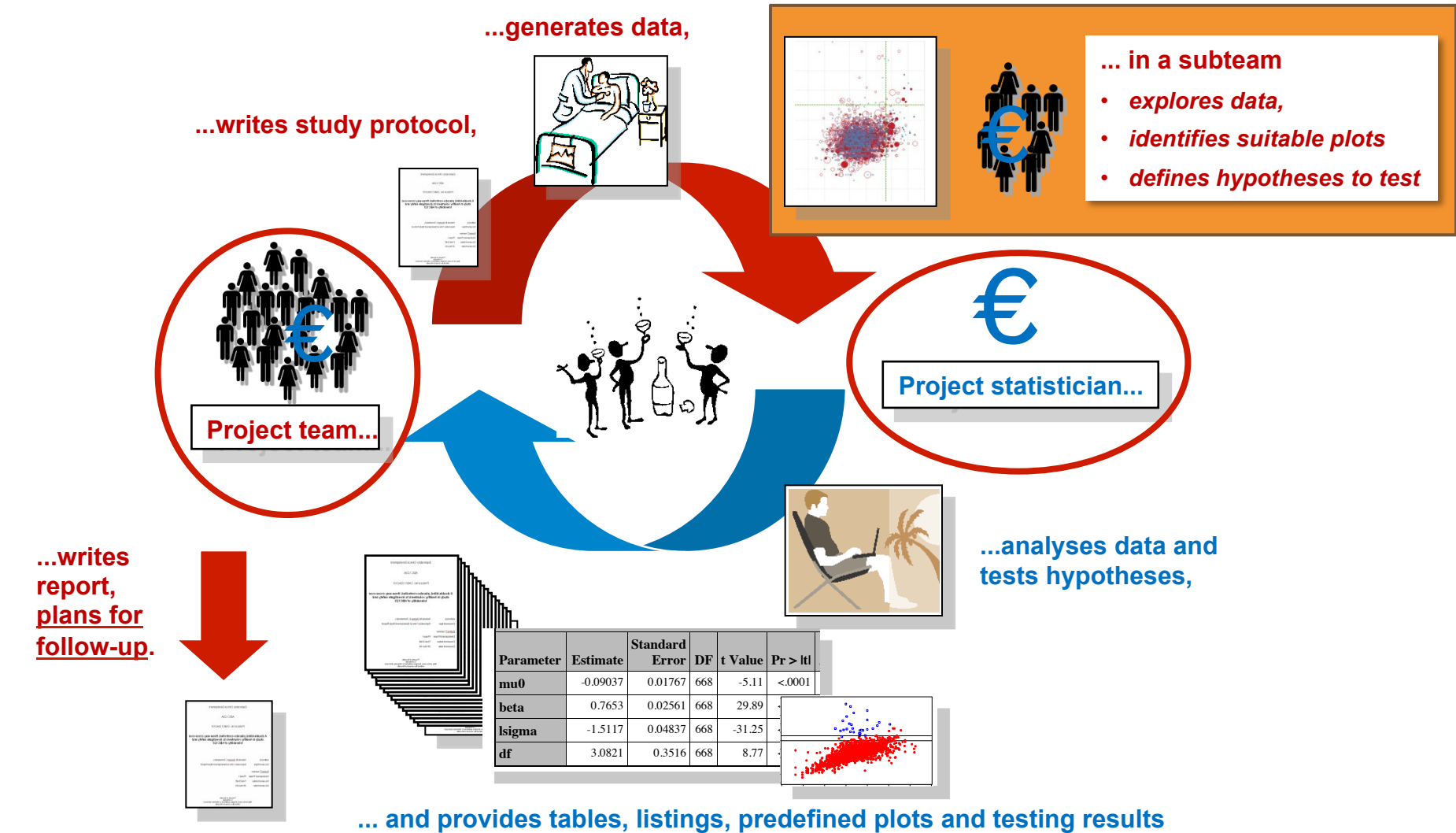
Safety data assessment in clinical studies

Standard process



Safety data assessment using interactive graphics

Adding one step can change a lot!



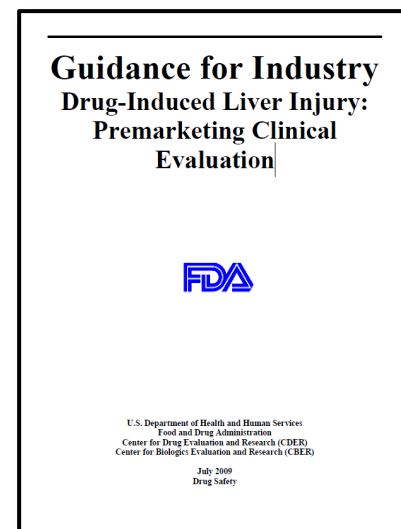
Case study: assessing liver safety with Spotfire

Hy's law

A short introduction

Definition

1. The drug causes hepatocellular injury, generally shown by a **higher incidence of 3-fold or greater elevations above the ULN of ALT or AST** than the (nonhepatotoxic) control drug or placebo
2. Among trial subjects showing such AT elevations, often with ATs much greater than 3xULN, one or more also show **elevation of serum TBL to >2xULN, without initial findings of cholestasis** (elevated serum ALP)
3. **No other reason can be found** to explain the combination of increased AT and TBL, such as viral hepatitis A, B, or C; preexisting or acute liver disease; or another drug capable of causing the observed injury



“Finding one Hy’s Law case in the clinical trial database is worrisome; finding two is considered highly predictive that the drug has the potential to cause severe DILI when given to a larger population.”