Bilirubin is produced within the reticuloendothelial system through a process called hemolysis and is a by-product resulting from the breakdown of hemoglobin in red blood cells. The liver filters bilirubin from the body into the bile, which gives its color, and a small amount is normally found in serum. An excess of red blood cell destruction, or a reduced capacity of the liver to excrete the normal amounts of bilirubin, will result in elevated levels and is important in evaluating hemolytic anemias, hyperbilirubinemia and liver function.

A Manual of Laboratory Diagnostic Tests by Frances Fischbach 3rd Ed.

Pages 280-281

Food and Drug Administration, HHS Part 50—Protection of Human Subjects
21 CFR Part 112 Investigational New Drug Application
45 CFR Part 46 Protection of Human Subjects
Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice
ICH E9 Statistical Principles for Clinical Trials
FDA Providing Regulatory Submissions in Electronic Format: Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

List of Standards, Guidance, Regulation, etc.

FDA eCTD Technical Conformance Guide
FDA Statistical Software Clarifying Statement
FDA Study Data Standards for Regulatory Submissions Position Statement
FDA Data Standards Catalog
SDTM Model Documents
SDTM and ADaM Implementation Guides
FDA Validator Rules Final Dec 2017 v1.2
FDA Technical Rejection Criteria for Study Data
FDA Position Statement - Use of SI Units for Lab Tests
NIH, National Institutes of Health, U.S. Department of Health and Human Services, etc.

This poster will trace the path of a single piece of data and identify all the regulatory and standards compliance considerations that dot the landscape from initial data collection all the way through submission through the eCTD. We'll follow the journey of the lab parameter Total Bilirubin, NCI Thesaurus Code C38037, and affectionately known in this poster as “Bili”, while demonstrating every influencing factor in the standards and regulatory environment as Bili’s data values and metadata are transformed along the way from start to finish. Standards concepts of CDASH, SDTM and ADaM will be considered along with all the regulations defined in the FDA Data Standards Catalog. Other items will be demonstrated such as data anonymization and Define-XMLv2.0 which have an effect of transforming data or metadata for data sharing and submission. From start to finish, Bili’s journey is truly remarkable.

Bilirubin values are not likely to change but direct and quasi-identifiers may change to protect personally identifiable information for data sharing.