Meeting Minutes

CDISC-HL7 Stage I-B
April 10, 2008
11:00 am – 12:00 pm (EST)

Attendees / Affiliation

Dave Iberson-Hurst/CDISC (Co-Chair)
Jay Levine/FDA (Co-Chair)
Lisa Chatterjee/Digital Infusion
Richard Diamond/FDA
Julie Evans/CDISC
Patty Garvey/FDA
Terry Hardin/IBM
Wayne Kubick/Lincoln Technologies
Pierre Yves-Lastic/Sanofi
Mary Lenzen/Octagon
Saurin Mehta/Novartis
Armando Oliva/FDA
Jason Rock/Global Submit
Bill Rosen/Pfizer
Steve Ward/Eli Lilly
Lynn Walker
Diane Wold/GSK

Background

The Clinical Data Interchange Standards Consortium (CDISC) formed a Stage IB group to develop the requirements for the CDISC - Health Level 7 (HL7) Content to Message Project. It was agreed by FDA and CDISC to conduct a series of regular conference calls for sub-team members as the initial path forward on the CDISC HL7 IB activities.

It was agreed in the initial meeting of this group, that every 4th meeting would be open to the Regulated Clinical (RCIM) technical committee. This is the 4th meeting, therefore RCRIM was invited to participate in the meeting.

The purpose of this meeting will be to review and address the comments provided Stage II on the Study Participation specific storyboards.

Discussion

The following specific storyboards and comments were provided by Stage II.

- 1.5 Other Participating Organization
  - Add dates when these organization participate
  - Update organization information

- Stage IB accepted the comments. They will add start and stop dates and update organization information.

- There was a question whether an elaborate list of organizations were needed at this time. It was indicated that this information is not needed at this time, however all organization should be identified at implementation of the standards.

- Pierre-Yves raised concern about trying to include information about Investigational Review Boards (IRBs) and their approval processesi. Pierre-Yves stated that if FDA wants to have information about IRB approvals (e.g. dates of IRB approval), capturing the information in a multinational trial may be too complex. The multinational trial approval process varies depending on the countries as well as the many organizations involved such as government agencies, scientific boards, various ethics boards (national, regional, community or even hospital specific) and that each of these deliver different kind of approvals. He suggested that it might be appropriate only to track when final approval was obtained for a specific country.

- 1.6 Study Progress Report
  - Can be a combination of brand new subject or update information of a subject
  - Can be an update or bulk load

  - It was stated that new or updated information of a subject will be addressed; however the intention is not to create a disposition record for every subject, simply to submit whatever disposition records exist.

  - It was indicated that further clarification is needed on the definition of 'status' and 'disposition' of the subject to date. Disposition could be defined as when the subject leave the study. For example, an annual report will provide the subject status, but a disposition is when the subject leaves the study.

- There was not enough time to discuss the 'Final Disposition' and 'Aquaculture Study' storyboards.

Attachment: DRAFT HL7 CDISC Message Project

Drafted: PGarvey/4-16-2008
Approved: 5-6-2008

HL7 CDISC Message Project

The Business Case

The US Food and Drug Administration (FDA), as part of its mission to protect the public health[1], receives and processes vast amounts of information. A significant proportion of this information relates to the process of regulatory approval of drugs, biologics and medical devices and such information is currently received in a large number of disparate formats, both electronic and on paper, using a variety of formats and proprietary standards.

Significant steps have been taken to alleviate these issues with the development of standards that support electronic submissions in more consistent formats. Not all areas have been addressed and a significant proportion of that information is still paper-based. This situation makes it extremely difficult, if not impossible for example, to perform cross-study reviews or safety analyses throughout the entire life cycle, both pre and post approval, of a regulated product. Therefore the FDA wishes to receive, in regulatory submissions, standard clinical study information content in a standard exchange format. This approach is vital to the FDA strategic initiatives to integrate pre-marketing clinical trial data, post-marketing safety data, and product quality, manufacturing data to improve public health and patient safety.

Over the past few years, advances have been made in developing this standardised content through the development of the Biomedical Research Information Domain Group (BRIDG) model and the FDA feels the time is right to bring together many threads of work so as to take the next step and better integrate submitted information.

To meet this need the FDA wishes to combine CDISC content with the HL7 message exchange mechanisms.

The Clinical Data Interchange Standards Consortium (CDISC) is a global standards development organization with an open, consensus-based process and is the preferred semantic standard for medical research content. CDISC has liaison A Status with ISO Technical Committee 215 and a charter agreement with HL7 with a commitment to harmonize the CDISC standards with the HL7 RIM via the BRIDG model. The BRIDG model was initiated by CDISC in 2004 for this purpose.

CDISC has developed the Study Data Tabulation Model (SDTM) which defines a standard structure for study data tabulations that are to be submitted as part of a product application to a regulatory authority. The SDTM is the standard adopted by FDA as the mechanism for exchanging study data. CDISC is in the process of

[1] by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.
Source: FDA Strategic Action Plan, 2007

developing other standards using the BRIDG model for other areas such as medical research protocols and study designs.

Health Level 7 (HL7) is the preferred electronic exchange format for healthcare information. It is an ANSI-accredited standards development organization with liaison A status with ISO Technical Committee 215. The HL7 exchange format is already used for other FDA messages that will carry content to the JANUS warehouse including the Structured Product Label (SPL), the Integrated Case Safety Report (ICSR) and Regulated Product Submission (RPS) messages. HL7 is the preferred electronic exchange format for healthcare information, per the Department of Health and Human Services.

By bringing the CDISC content together with the HL7 exchange mechanisms via the BRIDG and RIM the SDTM content will be combined with additional meta-data to meet the following needs:

- Overall improved Data Management in FDA
- Harmonize with HL7 standards for all structured regulated medical product information
- Prepare for eventual data integration with Electronic Health Records (EHRs) as they start being used for both Clinical Research and Surveillance

Improved Data Management in FDA

The current exchange standard for data content is the SAS Transport file (XPT). This method has limitations in that flat files do not inherently capture relationships between study data or between study data and study design as desired by FDA. Adding these relationships post-facto is invariably incomplete, done inconsistently, is time-consuming and inefficient. FDA would like to move away from the SAS Transport mechanism towards a more robust exchange standard for Clinical Observations that inherently relate clinical observations with each other (such as the HL7 ICSR) and with planned observations at the point of data collection so they can reliably and consistently be conveyed to FDA information systems. FDA recognizes that currently these important relationships are not often captured (or are captured inconsistently) at the point of data collection. However, as EHRs come into more widespread use, the opportunity to capture these relationships automatically at the point of collection will increase.

Harmonize with HL7 standards for all structured regulated medical product information

FDA is committed to harmonize all exchange standards for regulated product structured data with the HL7 RIM (using the Biomedical Research Integrated Domain Group (BRIDG) to achieve a more robust data model structured regulated product information.

Harmonizing study data exchange standard with the HL7 ICSR will provide a single data model for all pre- and post-marketing clinical observations. This will facilitate loading study data and post-marketing clinical observations into the JANUS data warehouse, which will in turn improve FDA's ability to analyze safety information throughout an entire medical product's life cycle.

Harmonization with the HL7 SPL standard provides a better way to associate clinical observations with medical product information. Although important for drugs, this will be particularly important for medical devices, biologics, and drug-

device combination products where model number, lot information, and other product information may be critically important to interpret causal relationships between specific medical products and the clinical observations associated with their use.

Prepare for eventual data integration with Electronic Health Records (EHRs) as they start being used for both Clinical Research and Surveillance

HL7 messages are the preferred exchange format for clinical observations captured within Electronic Health Record (EHR) systems. The Office of the National Coordinator for Health Information Technology (ONC-HIT), part of Health and Human Services, is facilitating a national effort to achieve EHRs for everyone in the U.S. by 2014. Efforts are also underway to enable the use of EHR systems to support data collection for clinical research (e.g. the Electronic Health Record – Clinical Research (EHR-CR) working group) as well as post-marketing surveillance. Having HL7 messages for both clinical research and post-marketing data will facilitate the use of EHRs for clinical research and surveillance purposes, which will in turn facilitate data exchange between EHR systems, third party clinical research and post-marketing surveillance databases, and FDA.

The CDISC-HL7 project and the resulting messages will also:

1. Enhance FDA regulatory decision making and address complex public health questions through improved data management to improve public health.
2. Standardize data exchange and terminology standards to facilitate data aggregation, analysis, data mining and signal detection.
3. Reduce the duplication of information received at the FDA especially when the data are received more than once in differing formats.
4. Allow reviewers to view the data that provides a better understanding of what happened to subjects and provide greater capability to analyze the data.
5. Improve access to aggregate data through the use of the JANUS data warehouse.
6. Support the FDA Critical Path Initiatives for the development of safer, more effective products.
7. Provide FDA with a mechanism to detect patterns (signal detection), determine the pace (problem scale) and know the place (specifically where) risks or emergencies are present.

FDA intends to update its progress towards meeting these goals through periodic updates to the Prescription Drug User Fee Act IV Information Technology 5-Year Plan.[2]

[2] http://www.fda.gov/ohrms/dockets/dockets/07d0481/07d0481.html

Study Participation

Summary of Requirement

The Study Participation message is intended to inform the agency about all experimental subjects, investigators, and other relevant entities that are involved in the conduct of an individual study. This information if often provided:

1. At the start of the study
2. As part of a subsequent update on that study
3. As part of the final study report

At each of the above time points the message could contain some or all of the following information:

1. The organizations involved within the study (e.g. sponsor, IND holders, CROs, central labs, safety monitoring boards, data management organizations etc.)
2. Subject demographics
3. Subject disposition information
4. Investigator participation

At the present time information on the organizations is passed to the agency in an ad hoc fashion at a variety of time points and encompassed within electronic free text documents such as PDF making the information difficult to access.

Information on subjects and investigators is currently contained within annual reports and protocol amendments[3]. These again are currently electronic PDF documents making access to the information difficult. Investigator information is also supplied as using Form 1572s. As such there is a desire to link to the clinical investigator information held within FIREBIRD.

It should be noted that this message deals with Study-level information. Investigational application level information (e.g. IND, IDE, INAD) is handled by the RPS message.

Storyboards

1. 1 Investigator Information

Acme Pharmaceuticals would like to submit investigator information for the principal investigator and investigator for three new sites for their 10-site multicenter trial – Study NCT99999999. The company does not require their investigators to use a centralized clinical investigator registry which FDA can access (e.g. FIREBIRD) so they submit the information directly to FDA. They will use the study participation message to provide the site information, investigator names and qualification information similar to what is currently captured in FDA Form 1572.

[3] See 21 CFR Part 312.30 Protocol Amendments and 312.33 IND Annual Reports

1.2 Updated Investigator Information

Acme Pharmaceuticals has identified the remaining seven site investigators for their study NCT99999999. Furthermore, the original investigator at site 3 has resigned and has been replaced and investigator at site 5 has changed his address. Acme provides updated site investigator information using the study participation message.

1.3 Populate Clinical Investigator Registry

FDA has received and reviewed investigator qualification information for Acme Pharmaceutical Study NCT99999999. FDA will use the study participation message to update the centralized clinical investigator registry (FIREBIRD) with investigator qualification information.

1.4 Inspection Results

FDA has inspected investigator/site number 4 for study NCT99999999. FDA uses the study participation message to transmit inspection results to the centralized clinical investigator registry (FIREBIRD).

1.5 Other Participating Organizations

Acme has contracted the services of several outside organizations to support the planned activities associated with Study NCT99999999. These include

- a contract research organization (CRO) to support data acquisition, storage, and analysis;
- a central laboratory vendor to process all laboratory samples;
- a central imaging vendor at a nearby academic institution to provide all interpretations of MRIs collected during the study
- site-specific Investigational Review Boards, including date of IRB approval, if available
- a central ECG vendor to interpret all electrocardiograms
- a Data Safety Monitoring Board to review blinded safety information in real time

Acme sends the information to FDA using the study participation message.

(see Appendix 1 for a more complete list of organizations that are commonly associated with a study.)

- Add dates when these organization participate
- Update organization information

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1.6 Study Progress Report

New Wave Pharmaceutical has committed to perform a phase 4 multi-center study (NCT88888888) to investigate the effects of their recently approved Drug B on cognitive function and level of alertness, because of inconclusive causal reports in phase 3 clinical trials of drowsiness and motor vehicle accidents. As part of their phase 4 commitment, they must notify the FDA annually on the progress associated with conducting the trial. With their annual report submission, they can use the study participation message to identify for each

study the subjects enrolled to date, including all relevant demographic information as currently defined by the DM Domain in the CDISC SDTM standard, the investigational site for each subject, and the status and disposition of the subject to date according to the CDISC DS domain, as well as the cutoff date used for the report.

- Can be a combination of brand new subject or update information of a subject
- Can be an update or bulk load

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1.7 Final Disposition

New Wave Pharmaceutical's study NCT88888888 is now complete. They submit all final disposition information of all subjects with the final study report using the study participation message according to the CDISC SDTM DS domain.

- Need to "tag" data as final (no more updates) – not limited to disposition
- There may never be a "final" disposition

1.8 Aquaculture Study

Government Agency Aqua plans to study the effectiveness of a new immersion product, Drug A, administered at 100 mg/L for 15 minutes daily on alternative days to control mortality in coolwater species of freshwater-reared finfish due to Disease X caused by bacteria *Fish pathogen*. [Study design details to be included in the study design storyboards] Six tanks of fish were studied. Tank "demographic" parameters included tank dimensions, maximum total volume, and species of fish the tank contained. One tank "dropped out" because an unacceptable number of fish jumped out during the study (>15% by protocol). Another tank also "dropped out" because the drain pipe was accidentally left open after routine cleaning. The study participation message will carry tank participation information, and the relationship between the tank (experimental unit) and the fish treated (organism of interest).

- After further discussion, it was recommended that Stage IB re-review this storyboard and revise or delete the storyboard as appropriate.

1.9 Device Performance Study

[not sure if such a study would ever require this message, as the intended study device per protocol should always match exactly what was actually studied (?)]

1.10 Sunburn

Acme Pharmaceuticals studied the effects of their new topical pharmaceutical product, Drug A in two available strengths, a 1% topical lotion and a 5% topical lotion, compared with placebo lotion for treatment of sunburn in Study A1234 [design details to be provided in study design storyboard]. One hundred (100) subject were treated across 10 centers. Each subject treated three sunburned patches of skin, one each with each experimental treatment. Two dropped out due to local adverse events. Three dropped out due to systemic adverse events.

Two subjects only treated two sites and one subject only treated one site. Two were lost to follow-up. Subject participation and disposition information is provided in the subject participation message with the final study report, along with the relationships between subjects and actual treatment sites.

Map to SDTM

Data for the message maps to the existing SDTM DM and DS domains.

Note: A more detailed map would be useful to assist those working with SDTM today to see where things are going in the new messages. Will also allow for a cross check to see if all of SDTM is being carried by the combined set of 4 messages.

Domain Analysis Model etc

Note: Diane's information model and other supporting artifacts in here

Study Design

Summary of Requirement

Notes from previous document

*A **New Protocol** submission contains information about what will be done, including planned analyses, etc. The **study design** message will transport this information in a standardized format: study summary, trial design, eligibility criteria, and statistical analysis plan.*

1. *Study summary: The SDTM Trial Summary (TS) domain is structured in parameter/value format. CDISC has produced controlled terminology (parameters and valid value lists), but SDTM contains (in the not-yet-finalized SDTMIG 3.1.2) only a recommendation about which parameters should be submitted.*
2. *Trial design: The SDTM Trial Arms (TA) and Trial Elements (TE) domains contain information roughly equivalent to the study schema diagrams in common use. The SDTM Trial Visits domain contains information about planned visits. The TDM team has modeled the Schedule of Activities (what is to happen when) and harmonized with the BRIDG, but this information has not yet been implemented, other than the information in the SDTM Trial Visits domain. SDTM subject data domains make use of planned timepoints, but there are not currently trial-level SDTM domains for planned timepoints.*
3. *Eligibility criteria: The SDTM Trial Inclusion/Exclusion (TI) domain contains the text of eligibility criteria (actually, 200 characters of the text), along with a variable which indicates whether the criterion is an inclusion or an exclusion criterion. Work on structuring eligibility criteria is ongoing within the ASPIRE project, but is at a fairly early stage. The HL7 message will link to values for planned observations and subject chararacteristics that correspond to the eligibility criteria.]*
4. *Statistical Analysis Plan (to be included in a future version): Some modeling work has been done in this area, but nothing is published, or is near implementation-ready.*

Storyboards

Note: Exist in a separate document at the moment

Map to SDTM

Domain Analysis Model etc

Subject Data

Summary of Requirement

Notes from previous document

*A **Study Report** submission (interim or final) contains the results. The **Study Participation** and the **Subject Data** messages will transport this information, including collected study data and derived data for analysis.*

1. *Study Participation information as described above.*
2. *Study Data*
   a. *Study data will need to be submitted in a form consistent with the HL7v3 ICSR. The message will need to contain all of the data contained in the following existing CDISC standards*
      i. *Case Report Tabulations: The subject data domains of the SDTM contain all the collected data, as well as coded and standardized versions of the collected data (e.g., MedDRA codes, numeric results converted to standard units, scores of questionnaire data), and some particularly useful derived data (e.g, timing converted from date to study day format, flagging of baseline values, which analysis populations a subject belongs to).*
      ii. *Analysis Datasets (to be included in a future version): These are the ADaM datasets that were used to produce the key results of the analysis. "Key" is defined by negotiation between sponsor and FDA. There is at least one analysis dataset, the ADSL dataset which contains one record per subject. ADaM datasets contain a mixture of collected and derived data, including a number of flags and other features that are helpful to FDA statistical reviewers in reproducing results and exploring their sensitivity and robustness.*
      iii. *Dataset Definition Tables: The CRT-DDS (more commonly known as the define.xml) contains metadata about the SDTM and ADaM datasets, links from the dataset to precursor information (annotated CRF pages for SDTM, other datasets for ADaM), and derivation information. Analysis Results metadata was demonstrated in the SDTM/ADaM pilot, and is being incorporated into the define.xml standard.*
   b. *The harmonization of the ICSR and the proposed study data message may require changes to the ICSR.*

Storyboards

Map to SDTM

Domain Analysis Model etc

HL7 ICSR

1. HL7 ICSR
2. An **Expedited Adverse Event Report** contains information about an adverse event that must be reported shortly after it is observed. The HL7 ICSR will transport this information.

Gaps in BRIDG

The gaps that need to be filled in BRIDG. Summary of the information held above

Recommendations

1. 5th Message to cover the Study Completion (study status) use case

Appendix 1 – Study Roles and Responsibilities for Organizations

Title	Description
Sponsor	The individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.
IND Owner	The organization that submitted the IND (investigational new drug) application to the FDA.
Central Lab vendor	The responsible party for providing central laboratory services (routine clinical pathology, special diagnostic biomarkers, cytology, histopathology, histomorphometry, genotyping and genomics/sample storage). These responsibilities include acquisition, analysis, data management and results delivery.
Central ECG vendor	The responsible party for providing central ECG services (resting, continuous 12-lead). These responsibilities include acquisition, analysis, data management and results delivery.
Central Imaging vendor	The responsible party for providing central imaging services (CT scan, MRI, bone mineral density, routine X-rays, ultrasound, mammography, total body composition, echocardiography). These responsibilities include acquisition, analysis, data management and results delivery.
Central Diagnostic vendor (other)	The responsible party for providing other central diagnostic services. These responsibilities include acquisition, analysis, data management and results delivery.
Electronic Data Capture Hosting	The vendor responsible for providing the electronic data capture computer hosting service.
ePRO Vendor	The vendor responsible for providing the electronic patient-reported outcome (ePRO) service for the sponsor.
Pharmacology (PK – ADME)	The responsible party for providing the Pharmacokinetics or ADME (Absorption, Distribution, Metabolism and Excretion) analysis.
Protocol Preparation	The responsible party for preparing or reviewing protocol documents (i.e. protocol synopsis, protocol, protocol amendments, and protocol addenda)
Informed Consent Document	The responsible party for preparing or reviewing study-specific inform consent documents (ICDs), site-specific ICDs; amendments and supplementals – using

	content from the protocol, the risk profile and the country-specific ICD requirements.
CRF Development and CRF Instruction Guide	The responsible party for the review, design, draft, and/or development of study CRFs and the CRF instructions.
Translations of Protocol, ICD, CRF	The responsible party for performing the translations for the protocol, ICDs, IBs, CRFs, CRF instructions and potentially other study specific documents.
Printing, Binding, and Shipping (Non-Study Drug Supplies)	The responsible party for printing, binding, and shipping of the protocol, CRFs, regulatory packages (e.g. IB, 1572 forms, ICD, etc.) and other study-related documents to sites.
Site Qualifications	The responsible party for developing a list of potential sites and the subsequent screening and qualifying of the selected sites
Site Contracts and Budgets	The responsible party for obtaining site confidentiality agreements, negotiating site budgets, preparing, negotiating and executing site letter of agreements, and paying investigator sites per initial budget.
Site Regulatory Documents	The responsible party for the preparation, collection, and submission of site regulatory documents. This includes the tracking the submissions of the document versions and approval.
Institutional Review Board (IRB)	The responsible party or parties acting as an independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a study.
Investigator Meeting and Adjunct Clinical Training	The responsible party for the investigator meetings or adjunct clinical training.
Site Initiation Visits	The responsible party for conducting site initiation visits.
Site Monitoring	The responsible party for routine site monitoring visits including (but not limited to) the review, verification of the following: visit data; drug accountability, reconciliation, and return; informed consent documents; and running records (e.g. adverse events, concomitant medication).
Site Communication / Management	The responsible party for routine site communication / management. This will include the supervision and monitoring the progress of the study as well as the participation of the investigators to ascertain and verify the compliance of the investigators with the protocol, maintenance of the investigator documents, proper drug accountability / reconciliation and regulatory requirements.
Adverse Experience Reporting	The responsible party for collection of serious adverse events (SAEs) and regulatory reporting. This includes site compliance,

	safety mailing, patient narratives, trial level safety review, periodic reports and blinding and unblinding subject treatment.
Project Management	The responsible party for general project management of the study
Quality Assurance Audits of Investigator Sites	The responsible party for QA audits of the investigator sites.
Close-out Visits	The responsible party for close out visits including preparation and report completion.
Study Drug Management	The responsible party for Clinical Trial materials and related services. This includes: material planning, inventory management, study drug packaging, labeling, shipments, returns, destruction and monitoring / reconciliation of unblinding envelopes.
Interactive Voice Response System (IVRS)	The responsible party for developing and maintaining the IVRS system for usage in study enrollment, randomization and treatment assignments.
Data Management	The responsible party for data management (DM) activities. This includes the building and validating of the data entry and edit system; entry of CRF pages; data validation; coding terms; SAE review / reconciliation; database quality review; database lock; ancillary data integration and dataset delivery.
Statistical Analysis - Tables, Listings and Figures	The responsible party for statistical analyses and may include the preparation of the statistical analysis plan, and/or creating tables, figures and listings.
Clinical Study Reports and Manuscripts	The responsible party for preparing clinical study reports and/or manuscripts.
Investigator Brochure (IB)	The responsible party for preparing investigator brochures (IBs).
Clinical Endpoint Committee ("CEC")	The responsible party for providing services to support the Clinical Endpoint Committee (CEC) in making clinical endpoint determinations for the study.
Data Monitoring Committee	The responsible party for providing services to support the Data Monitoring Committee (DMC) for the study.

CDISC Content to Message Project

Storyboards

Study Participation Message

Investigator Information

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Updated Investigator Information

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Inspection Results

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Final Disposition

New Wave Pharmaceutical's study NCT88888888 is now complete. They submit all final disposition information of all subjects using the study participation message according to the CDISC SDTM DS domain.

Study on herds

Acme Pharmaceuticals have committed to perform a study involving a herd of cattle.

Device Performance Study

Sunburn

Part of the body