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Collaborative

Laboratory Information Network Cymru Programme (LINC)

LINC Glossary of Terms



LIMS Glossary of Terms

ABA-BAS-BAUS PVSA guidelines

Association of Biomedical Andrologists – British Andrology Society – British Association of Urological Surgeons – Laboratory Guidelines for Post-Vasectomy Semen Analysis 2016.

Association of Biomedical Andrologists (ABA)

Professional body for biomedical scientists working in the field of Andrology (now replaced by Association of Reproductive Scientists).

Association of Biomedical Andrologist's guidelines

Association of Biomedical Andrologists Laboratory Guidelines for Good Practice v3 2012

Association of Reproductive Scientists

Professional body for scientists working in the field of reproductive science.

Blood Safety and Quality Regulations (BSQR)

Regulations that came into force in 2005 and set standards for quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, aspects of the regulations apply to 'blood establishments' (the UK Blood Services) and Hospital Blood Banks. Click [here](#) for more details about Blood Safety and Quality Regulations from the JPAC web site

Business Rules Engine

A software system that executes one or more business rules in a runtime production environment.

Business Rules Logic

In computer software, business logic or domain logic is the part of the program that encodes the real-world business rules that determine how data can be created, stored, and changed. It is contrasted with the remainder of the software that might be concerned with lower-level details of managing a database or displaying the user interface, system infrastructure, or generally connecting various parts of the program. – See Test Set Rules.

Cancer Network Information System Cymru (CaNISC)

An online computer system that provides information for health professionals on cancer patients across Wales. The CaNISC system allows health professionals to access important clinical information wherever the patient receives specialist care and helps to provide the best possible care to cancer patients in Wales.

Clinical Data Repository (CDR)

The Clinical Data Repository is a solution being designed & built jointly by the NDR programme & Digital Health & Care Wales (DHCW). It will form part of the wider NDR Architecture and will act as a data storage solution for clinical data. It is the companion component to the National Data Store (NDS) with the NDS sitting on top of the CDR

Coded Comments (or Standard Comments)

Coded comments are a quick way of adding a standard set of comments to a result. Comments may offer insight from clinicians or laboratory personnel on interpreting data or suggesting follow-up tests. Coded comments may be added automatically by Test Set Rules or directly by the operator.

Complex algorithms

A program or formula that uses mathematical or logical methods and requires many lines of programming code to implement. Examples of complex algorithms include the eGFR and AKI calculators.

Computer System Validation (CSV)

Confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the requirements implemented through software can be consistently fulfilled.

Critical Success Factor (CSF)

Ensures consensus on project goals amongst stakeholders, clients and the project team.

Cutover Qualification (CQ)

Is a documented verification process to ensure that a product will work as planned in the live environment.

Data Migration

The process of migrating data to a system from another system.

Data Take-on

Data take-on refers to minimum data that must be migrated to the new LIMS to continue safe patient management and deliver business continuity as defined in Schedule 2.1 The Authority's Requirements.

Defect

An error in a product's source code or any other documentation.

Delta Changes

An absolute or percentage change of a value over a specified period of time, for example if a sodium measurement is 10 mmol/L higher or lower than a previous result it is said to have failed delta checks, Test Set Rules can then be applied to this result as appropriate.

Detection Limits

The detection limit, also known as the lower limit of detection or LOD (limit of detection), is the smallest amount of a substance that can be discriminated from its absence (a blank value) with a given level of confidence (generally 99 percent). The detection limit is calculated using the mean, standard deviation, and a confidence factor for the blank. The accuracy of the model used to forecast concentration from the raw analytical signal has an impact on the detection limit.

Deviation

Behaviour of a product that does not conform to expected behaviour.

Downstream system

A local clinical system electronically updated with pathology results.

Enterprise Master Patient Index (eMPI)

Enterprise Master Patient Index keeps patient data such as name, address, date of birth and sex, up-to-date and accurate. The eMPI works by linking all the records for an individual patient held across several information systems to a single “gold standard” patient identity record. Click [here](#) for more information on the NHS Wales technical infrastructure from the DHCW website.

Episode Number

A unique number used to identify each pathology investigation. One or more Test Sets or Accession numbers may be assigned to further define the examinations to be undertaken.

Fast Healthcare Interoperability Resources (FHIR)

A modern version of HL7, designed to enable information exchange to support the provision of healthcare in a wide variety of settings. The specification builds on and adapts modern, widely used RESTful practices to enable the provision of integrated healthcare across a wide range of teams and organizations.

Good Automated Manufacturing 5 (GAMP5)

A Risk-Based Approach to Compliant GxP Computerized Systems.

Good manufacturing practices (GMP)

The practices required to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices. These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use. The rules that govern each industry may differ significantly; however, the main purpose of GMP is always to prevent harm from occurring to the end user. Additional tenets include ensuring the end product is free from contamination, that it is consistent in its manufacture, that its manufacture has been well documented, that personnel are well trained, and that the product has been checked for quality more than just at the end phase. GMP is typically ensured through the effective use of a quality management system (QMS).

Handover

A process of handing over responsibility of the product to the customer after completion of testing.

Health Board (HB)

Local health boards are organisations within NHS Wales who are responsible for planning and delivering NHS services in their areas.

Health Level Seven International (HL7)

HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information.

These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognised as the most used in the world.

Historical Data

Historical data is data that must be retained and accessible to meet the legal and statutory requirements as set out in the guidelines referred to above.

Host Model

In computer networking, a host model is an option of designing the TCP/IP stack of a networking operating system like Microsoft Windows or Linux. When a unicast packet arrives at a host, IP must determine whether the packet is locally destined (its destination matches an address that is assigned to an interface of the host).

Human Tissue Authority (HTA)

An executive non-departmental public body of the Department of Health and Social Care. It regulates the removal, storage, use and disposal of human bodies, organs, and tissue.

Indices (specific to specimen type e.g., serum or plasma)

Analytical parameters that affect the validity of assay results. Serum indices include Lipaemia, Icterus and Haemolysis.

Information Governance (IG)

Information Governance is a framework, which supports how organisations and individuals manage the way information is handled. It applies to sensitive and personal information of employees, patients and service users, and to information related to the business of the organisation. Click [here](#) for more details on Information Governance from the DHCW website.

Installation Qualification (IQ)

Is a documented verification process that the product has been properly delivered, installed and configured according to standards set by the manufacturer or by an approved installation checklist.

ISO:9001

Internationally recognised set of standards for managing a quality management system.

Laboratory Information Management System (LIMS)

A computer system to manage pathology information and its exchange via various interfaces. Laboratory information includes details of investigations and sample workflow.

Laboratory Information Network Cymru (LINC)

LINC is a transformational programme that underpins the [Pathology Statement of Intent](#), which seeks to deliver modern, sustainable pathology services. A key component of this is to further standardise services, building on the work undertaken to date by the service. (See LINC Programme brief document).

Legacy Data

Patient data created by the previously used LIMS. Wales has a large amount of legacy data created in Telepath and Masterlab systems over a period of many years. Some of this data should be incorporated into the patient record of any future LIMS using an export – transform and load process, the remainder will be held in Legacy data repositories. All data should be readily accessible to appropriate LIMS users.

LINC Design Authority (LDA)

A panel of stakeholder representatives and subject matter experts that are responsible for assuring the delivery of LINC objectives and signing off deliverables.

Live Environment

The live, or production, environment of a system that will be used by End Users to conduct normal business.

Local Data Repository (LDR)

Held within the Health Boards – these will be linked to the NDR and hold datasets locally relevant to the requirements of the Health Board – sync'd to the NDR as needed.

Master Patient Index (MPI)

Can refer to a single registration system and all of its patients. It is also used as shorthand for Enterprise Master Patient Index (or eMPI), which is a database that brings together patient records from multiple registration systems.

Microsoft Active Directory ("NADEX")

A directory service developed by Microsoft for Windows domain networks. It is included in most Windows Server operating systems as a set of processes and services.

Microsoft Active Directory Federation Services (ADFS)

A software component developed by Microsoft, can run on Windows Server operating systems to provide users with single sign-on access to systems and applications located across organizational boundaries. It uses a claims-based access-control authorization model to maintain application security and to implement federated identity.

Middleware

Middleware is software provided by an analyser manufacturer to interface their analysers. In Wales, the most common middlewares are AMS (Abbott), Remisol (Beckman), CITM (Roche) and SIS (Sysmex). Middleware allows for sophisticated technical validation rules, QC packages and bespoke data analysis for the analysers connected to the middleware.

National Data Repository (NDR)

A programme of work underway to deliver a joined up National data resource to provide interoperability, a national view of data in Wales and the ability to provide additional advanced data tools.

National Intelligent Integrated Audit Solution (NIIAS)

Linked to clinical systems and can be used to analyse activity on these systems and report on instances where potentially inappropriate access has occurred.

National Pathology Exchange (NPEx)

NHS Wales intends to use the National Pathology Exchange (NPEx) to manage, both outbound and inbound send-away request for tests to and from Laboratories outside of Wales.

Open Database Connectivity (ODBC)

An open standard Application Programming Interface (API) for accessing a database.

Operational Qualification (OQ)

A documented verification process that involves testing the product and making sure it performs as specified, within operating ranges as listed by the manufacturer. All aspects of the equipment receive individual testing and the tester documents the proper operation of each.

Order of Draw

In phlebotomy Order of Draw is a system of collecting more than one tube of blood at the same time from a patient while reducing instances of cross-contamination. Contamination may occur when the syringe contacts microorganisms, additives or blood mixed with additives in previous test tubes.

Organisational Unit (OU)

In computing, an organizational unit (OU) provides a way of classifying objects located in directories, or names in a digital certificate hierarchy, typically used either to differentiate between objects with the same name or to parcel out authority to create and manage objects

Pathology Statement of Intent (PSOI)

A document written by Welsh Government that addresses the current challenges facing Pathology services in Wales. It identifies eight priority areas where new strategic approaches are required to facilitate the development of high quality, effective and resilient Pathology services. The 2019 PSOI may be found [here](#).

Patient Administration Systems (PAS)

Records the patient's demographics and details all patient contact with the hospital, both outpatient and inpatient

Patient type

Patient related information describing the source of the request, patient types include inpatient (patients located in hospital wards), GP (General practice patients in the community), accident and emergency, critical care, day case and outpatient. Rules may be applied to results based on the above patient types as appropriate.

Performance Qualification (PQ)

A documented verification process to assure that a product(s) is working within the accepted range as specified and performs as expected under real conditions.

All instruments are tested together according to a detailed test plan and must generate reproducible results.

Point of Care Testing (POCT)

A service that brings pathology testing for certain conditions to the clinical areas thus improving turnaround time for these tests. Clinical personnel perform POCT testing following adequate training as provided by the Laboratory or Point of care coordinating team.

Profile Code

Groups of tests ordered under one profile code, allowing for faster and easier processing of standard testing procedures.

Public Sector Broadband Aggregation (PSBA)

A managed network which connects nearly all areas of the public sector in Wales, including the NHS, to a private network.

Quality Management System (QMS)

A system that is made up of controlled procedures that manages the quality of an organisation, project, or programme.

Reference range

Test Item information defining the reference range to be included in the pathology report next to the test item value (if needed). They are required to indicate if results fall within what is considered the reference interval for a specific population. Reference ranges may be age, sex or analytical platform specific.

Reflex test

A reflex test in a laboratory setting is a test that the laboratory automatically adds on based on the result of the initial requested test. The add on rules may be held in LIMS or middleware.

Release

A term used to refer to new software patches or versions that are implemented.

Representational state transfer (REST)

A software architectural style that defines a set of constraints to be used for creating Web services. Web services that conform to the REST architectural style, called RESTful Web services, provide interoperability between computer systems on the Internet.

Request Type

Request related information describing the type of the request. Request types include Anonymous, EQA, Private Patient, NHS, etc. Rules may be applied to results based on the above request types as appropriate.

Role Based Access Control (RBAC)

Used in computer security to restrict system access to authorised users.

Server Message Block (SMB)

Server Message Block is a network communication protocol for providing shared access to files, printers, and serial ports between nodes on a network.

One version of which was also known as Common Internet File System (CIFS).

Service Level Agreement (SLA)

An agreement between a supplier and the customer on setting out conditions for the management of the service provided.

Service Oriented Architecture (SOA)

A style of software design where services are provided to the other components by application components, through a communication protocol over a network.

Simple Object Access Protocol (SOAP)

A messaging protocol specification for exchanging structured information in the implementation of web services in computer networks. Its purpose is to provide extensibility, neutrality, verbosity, and independence.

Specimen Type

The specimen type describes the type of tube and preservative required for a specific test. Examples of Specimen types include Serum-Gel, Plasma-Heparin and K2-EDTA.

Structured Query Language (SQL)

A domain-specific language used in programming and designed for managing data held in a relational database management system.

Technical Validation (Instrument results – The Grid)

Technical Validation is a process used to review analyser results prior to them being release into LIMS for further processing. Technical Validation can be configured to hold all results for manual release, only some results based on ranges or flag criteria or black box mode where no results are held at all.

Telephone limits (Panic Ranges)

Also called the panic range, test Item information defining the level at which a result should be placed in the Telephoning list.

Test Environment

A replica(s) of a LIVE environment specifically managed for testing requirements.

Test Item

A container for a single item of test information, details stored include the test code, test name, units, decimal places, acceptable, reference and panic ranges for every scenario where this test is used.

Test Set

A container for one or more Test Items. Test Sets can have specimen types.

Test Set Rules (Test Set Actions and Conditions)

A rule in LIMS is a set of instructions to be executed when certain conditions are met. All the individual rules contribute to a very large rule-base which instructs LIMS how to process its business in a pre-defined manner.

Testable Requirement

A requirement that can be tested against objective metrics or specified behaviour.

The Association for Clinical Biochemistry and Laboratory Medicine (ACB)

This organisation is the major body for clinical biochemistry, immunology, and microbiology in the United Kingdom. Click [here](#) for more details from the ACB web site.

The Authority

Contractual term referring to NHS Wales and its constituent organisations.

Titres

A Titre is a way of expressing concentration of a substance. Titre testing employs serial dilution to obtain approximate quantitative information from an analytical procedure that inherently only evaluates as positive or negative.

Training Environment

The software and hardware environment (i.e., computers and software applications) necessary for the performance and receipt of the training services and replicates the live environment

Transmission Control Protocol (TCP)

One of the main protocols of the Internet protocol suite. It originated in the initial network implementation in which it complemented the Internet Protocol (IP). Therefore, the entire suite is commonly referred to as TCP/IP. TCP provides reliable, ordered, and error-checked delivery of a stream of octets (bytes) between applications running on hosts communicating via an IP network.

United Kingdom Accreditation Service (UKAS)

UKAS is responsible for determining the technical competence and integrity of organisations such as those offering testing, calibration, and certification services. All NHS Pathology Laboratories in Wales are required to be enrolled in the UKAS Medical laboratory inspection service. UKAS inspects medical laboratories for compliance to ISO standard 15189. Click [here](#) for more details about medical laboratory testing from the UKAS web site.

Untestable requirement

A requirement that cannot be tested against objective metrics or specified behaviour.

User Acceptance Testing (UAT)

A type of testing performed by the client or service to certify a computer system is fit for purpose and meets the agreed requirements. Testing should be evidenced by scenarios and scripts.

Verification Queue

A list of results for review by a technically or clinically qualified staff member. Results are filtered into verification queues based on rules and verification queue capture ranges.

Wales Pathology Handbook (WPH)

A knowledge service within the Welsh national information architecture. It provides national and local catalogues of requestable tests, rules, and guidance for electronic requesting (via the Welsh Clinical Portal (WCP) and GP systems) and a web-based knowledge resource for all clinical departments.

Welsh Demographic Service (WDS)

Part of a set of services to manage administrative information (demographic data) for NHS patients in Wales.

Welsh Reference Data & Terminology Service (WRTS)

The Welsh Reference Data and Terminology Service maintains reference data on behalf of NHS Wales. The service distributes Systematised Nomenclature of Medicine - Clinical Terms (SNOMED CT) and provides a central repository for national reference data.

Welsh Results Reporting Service (WRRS)

Allows users of the Welsh Clinical Portal to view diagnostic reports and requests for their patients, regardless of where they are produced.

WHO Guidelines

A WHO guideline is defined broadly as any information product developed by WHO that contains recommendations for clinical practice or public health policy. Recommendations are statements designed to help end-users make informed decisions on whether, when and how to undertake specific actions such as clinical interventions, diagnostic tests or public health measures, with the aim of achieving the best possible individual or collective health outcomes. Click [here](#) for more detail on WHO guidelines from the WHO website.