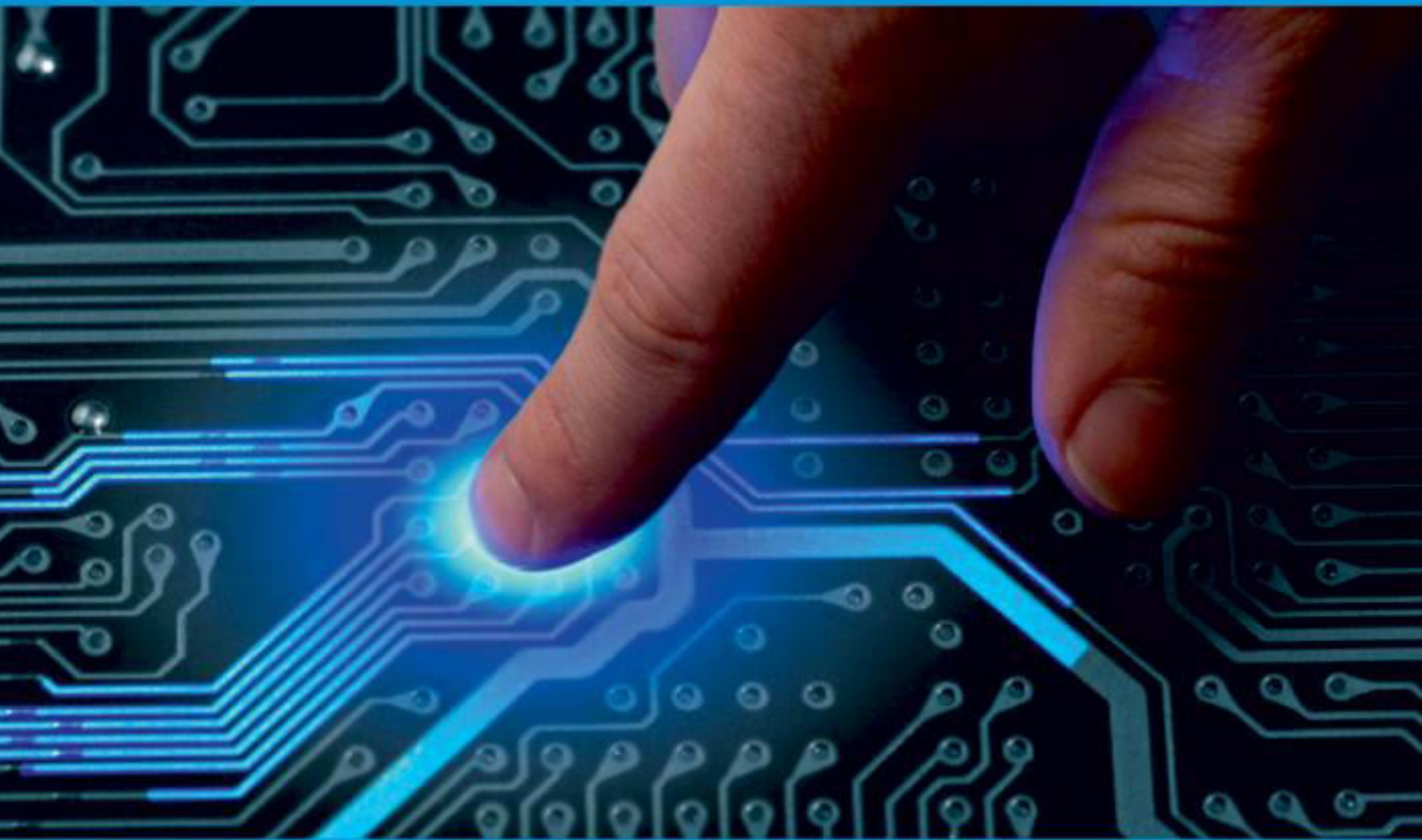




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Big Data-Aware Ontology Development for Medical Test Devices in LabHub

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ABSTRACT: Medical laboratories play a crucial role in diagnosing and treating diseases, relying on medical test devices to detect abnormalities. However, anomalies can arise due to environmental factors or human error, impacting test results. Traditionally, managing these anomalies requires manual intervention. LabHub, a novel intelligent laboratory system, leverages big data, semantic web, machine learning, and IoT technologies to automatically detect and prevent anomalies within laboratories. This work proposes a big data-aware ontology development methodology for the Medical Test Device Ontology (MTDO). The MTDO serves as the knowledge base for LabHub, allowing it to process data from diverse test devices operating under varying conditions.

KEYWORDS: Big data; semantic web; data-awareness; ontology development; health information systems.

I. INTRODUCTION

Healthcare domain is a huge and complex ecosystem where various organizations, institutions and also individuals get services and provide services at the same time. In addition, the facts that the individuals' health records start before their births and are still kept after their deaths and health services are government-provided for each citizen cause not only institutional but also personal health data to be quite huge.

First generation Health Information Systems (HIS) were developed to record the administrative data such as demographic and insurance information of patients. Although every new application in health domain can result with permanent disabilities or fatal consequences, software and hardware developments in information and communication technologies, although slower than other industrial areas, lead to a trend towards new generation data processing applications in healthcare.

New generation HISs such as Clinical Information Systems (CISs), Laboratory Information Management Systems (LIMSs), Decision Support Systems (DSSs), Radiology Information Systems (RISs) aim to collect, store, query, process domain-related data, and extract new information from these processed data by using new technologies such as IoT, big data, artificial intelligence, semantic web, machine learning, image processing and etc.

Medical tests are one of the primary medical practices used to diagnose or to monitor the treatment process for an individual's health status. Performing any medical test accurately and effectively as fast as possible with the lowest cost is under the responsibility of medical laboratories.

The medical laboratories, where huge amounts of data are produced, have used information systems to record medical test results and to reduce costs such as stock control. However, in recent years, laboratory processes, starting with taking samples from the patients to end with obtaining the results from the medical device, have begun to be managed by LIMS thanks to IoT technologies. In order to obtain the correct result, it is aimed to make the process autonomous and to monitor the process from taking the sample through sending the result to HIS. As an example, information about which physician requests the cholesterol test for a patient, what time the sample is taken by which laboratory staff, which sample tube contains the sample, which device is used for analyzing the sample, when the result is obtained can be provided and the result can be conveyed to the physician requested the test and to the patient who is the owner of the sample with less or without any human interaction.

The anomalies seen in the test results do not always mean health problems about patients. In the laboratory processes, which are classified as pre-analytical, analytical and post-analytical phases, errors, in other words anomalies, may occur due to components such as water quality, electrical current continuity, refrigerators in which chemicals and samples are kept, ambient temperature, ambient humidity, and etc.

LabHub, a new generation intelligent medical laboratory information management system, is developed to detect the anomalies that may occur depending on the conditions of the laboratory environment and can affect the medical test results, to prevent these anomalies and to provide preventive maintenance services for maintenance and calibration of medical devices in the laboratory. The system collects data coming from the sensors on the devices and the IoLT Plug-

in developed by us, process these data and warn the laboratory staff by predicting possible anomaly situations. For this purpose, a big data-aware ontology-based system is designed with the aim of providing services supported by machine learning algorithms.

In this study, the knowledge base modelling methodology of LabHub developed as big data-aware laboratory information management system is presented. The structure of the article is as follows. Section 2 deals with LIMS and HIS literature. Section 3 explains the motivation of the LabHub Platform and the information technologies suit for the motivation. In Section 4, big data-aware ontology development methodology is defined on MTDO (Medical Test Device Ontology) that models the knowledge base of the system. Finally, conclusions and future works are presented.

II. RELATED WORK

Health Information Systems (HIS) have unique, complex, dynamic features which differ significantly from other industrial information systems, because of leading permanent disabilities and fatal consequences [1]. The aims of using HIS in health organizations can be summarized as enhancing the quality of health care provided to patients and maximizing their comfort while minimizing the costs involved [2].

The data about patient recorded in HISs is defined as Electronic Health Record (EHR) with the purposes of setting objectives and planning patient care, documenting the delivery of care and assessing the outcomes of care [3]. One of the challenges faced with EHR is the interoperability problem [4,5] defined as the ability of exchanging EHRs between HISs produced by different institutions. To overcome interoperability problem, it was focused on clinical coding and data standardization studies [6]. Since the required EHR cannot be semantically defined with Health Information Standards, the researches has been shifted to develop domain-specific ontologies considering the reasoning and inferencing capabilities of semantic web [7]. There are various health information standards developed for different purposes to define clinical-based domains like SNOMED-CT (Systemized Nomenclature of Medicine-Clinical Terms) [8], ICD (International Classification of Diseases) [9], FMA (Foundation Model of Anatomy) [10], and RadLex (Radiology Lexicon) [11]. All these common used standards are hosted as an ontology on BioPortal [12]. BioPortal is an online repository of over 500 biomedical ontologies which cover a subject domain.

The fact that the health is so huge and complex that it cannot be modelled as a single system has led to the development of sub-systems, in other words clinical-specific systems, which simulate HIS structure in the real world. In addition to the clinical-based EHRs, it is observed that Clinical Decision Support Systems (CDSSs) that support the diagnostic process have been developed. Despite the almost half a century history of CDSSs, several barriers like representing and reasoning of medical knowledge still effect the implementation of CDSSs [13]. One of the essential requirements of CDSSs is knowledge base which have to be modeled accurately, efficiently to serve effectively [14]. For example, a hybrid model for decision making is presented for neuropsychological diagnosis of Alzheimer's disease [15]. An improved computer aided diagnosis system developed for in-experienced radiologists and medical students to diagnosis brain tumors from radiology images by using artificial neural network is explained in another study [16]. One more example can be given as an intelligent decision making system for breast cancer which uses ontology for semantic representation of breast cancer knowledge model is introduced [17].

Semantic Web as the extension of the current web leads to a better collaboration between computers and humans with giving well-defined meaning of information [18]. New information can be obtained from the existing information by the inference and reasoning ability offered by the semantic web technologies. Ontology is a description of entities and their properties, relationships, and constraints expressed via axioms [19]. Domain ontologies [20] define conceptualizations that are specific for a particular domain. As mentioned before, there are various studies in which medical domain specific ontologies have been developed.

IoT technologies are one of the research topics of information technologies which are being used widely in the health domain [21]. Studies have been carried out to monitor the health status of patients by wearable devices and to manage health services with traceable devices [22-24]. IoT devices continuously generate structured, semi-structured and unstructured data named as big data. Processing and analyzing big data to get valuable information is a difficult process because of its complexity [25,26].

Machine learning is the process of creating a model from sample data to predict results or to categorize with new data. Although there are a lot of machine learning applications in the healthcare domain, predictive models for more efficient and better quality care, improving upon patient risk score systems, streamlining hospital operations can be given as examples [27,28]. Anomaly detection is the process to determine items or events that do not conform to an expected behavior in a dataset [29]. The first applications of anomaly detection were carried out for the security risks in information technologies [30].

LabHub is a HIS that aims to provide a solution by using machine learning, semantic web and IoT technologies under the same framework for detect anomalies that may arise in medical laboratories due to the device or the variables in the environment where the device is located. The features of the system are mentioned in the following section.

III. MATERIALS AND METHODS

Medical laboratories, also known as clinical laboratories, are as critical as clinical units for health domain due to analyzing the medical tests which are realized for advising the physician about individual’s health status during diagnosis or treatment processes. Medical laboratories are divided into subfields such as biochemistry, hematology, molecular biology, immunology, microbiology and etc. according to the issues focused on just as in the case of health domain.

Although health services are managed and controlled by governments all over the world, the health institutions that provide these services can be private health institutions as well as governmental institutions. This is also the case for medical laboratories. Clinical laboratories located in university or city hospitals, private hospitals and private laboratories can provide services under government supervision to perform medical tests.

Medical laboratory services are a set of complex procedures that significantly affect patient management and can be continuously improved, and each stage must be followed with a quality assurance system. First generation LIMSs were developed to record the medical test results [31]. Thanks to the flow of information provided by IoT technologies, LIMSs have updated their aims as monitoring the whole laboratory processes which begins with the sample taking from the patient and ends with the producing result [32]. Although LIMSs developed for this purpose have achieved great success, errors may still occur [33, 34]. Errors, also known as anomalies, may cause negative effects on the patient treatment and diagnosis, such as delay in test results, re-sampling from the patient, recall of the patient to the health institution, as well as cost-increasing consequences for the health institution [35].

Nowadays, monitoring and management of anomalies, that are caused by environmental variables, technical problems arise on devices or personnel faults, in values reflecting the health status of the individuals are carried out by human resources. However, in recent years, IoT technologies that perceive the environment and provide continuous data flow which could be processed has led to the design and development of smarter systems. This option offers a way to capture and manage anomalies in medical laboratories by an intelligent system. The components of a big data aware smart laboratory information system architecture developed for this purpose are given in the next subsection.

A. System Architecture

The laboratory analyzing process generally starts with the test request for the diagnosis and treatment of the patient, continues with sampling, for example transferring to the laboratory, admission to the laboratory, analytical study, and ends with the use of the result for the benefit of the patient after the result reporting. Each of these stages, which can also be classified as pre-analytical, analytical and post-analytical phases, are interrelated. Components, such as the water quality, the electrical current continuity, the coolers in which chemicals and samples are stored, the ambient temperature, humidity and etc., which are not actually seen in the laboratory but very important in infrastructure competence have a critical place in the process. LabHub is designed as a platform to increase the quality of medical laboratories by detecting anomalies that occurred because of environmental variables, calibration and maintenance deficiencies of medical devices in the laboratory and offering preventive maintenance services to prevent from anomalies. The components of LabHub architecture as seen in Fig. 1 are briefly explained in [36].

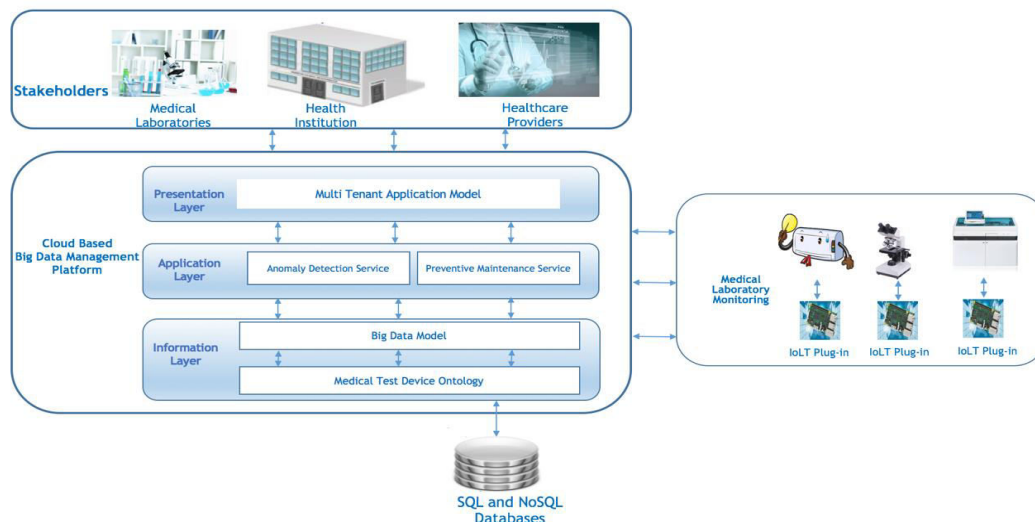


Fig 1. The components of LabHub System Architecture

The architecture is designed by taking care of alignment challenge in machine learning. As known, the medical laboratories host lots of devices in their environment. These devices may be the ones used for same test analysis but produced by different companies as well as the ones used for different test analysis. Nevertheless, data integration from different devices is required. Data integration is a defined as a trouble task because data from different sources can be heterogeneous in syntax, schema and semantics [37]. Therefore, LabHub uses knowledge base with high quality information by defining data through its relationships semantically to create a big data-aware information layer. The use of ontologies can enable data integration by supporting metadata representation, automatic data validation, conceptualization, and high-level semantic queries especially in the biomedical domain [37, 38]. MTDO (Medical Test Device Ontology) is developed for LabHub platform to define medical devices and its relationships with other related laboratory entities to detect anomalies as in the real world. Because each medical laboratory can be unique in terms of performed tests, owned medical devices and the environment of the devices located in. However, an extendable, flexible and data-aware knowledge base design is needed to ensure information sharing and reusability. For this purpose, a new approach for data-aware ontology development methodology is designed and implemented as explained in the following section.

B. *Big Data-aware Ontology Development: Medical Test Device Ontology*

Ontology defines the concepts and the relationships between concepts in a specific domain semantically. Although there are different ontology development methodologies in the literature, “Ontology Development 101: A Guide to Creating Your First Ontology” developed by Noy and McGuinness [39] is preferred methodology by commonly due to its domain-specific and reusability perspectives. It is not expected to be a single correct ontology defined for a particular field. For this reason, it may be possible to have many ontologies developed for the same domain. However, defining mappings between ontologies or ensuring reusability between ontologies to ensure interoperability is an important issue that should not be ignored.

When ontologies developed for health domain-specific are examined, it is seen that these ontologies only define domain-specific concepts but information systems where these ontologies are used as the key model of the knowledge base by leaving the traditional relational database are not encountered until last few years.

MTDO (Medical Test Device Ontology) is developed for modelling the knowledge base of LabHub Platform which aims to manage medical laboratory’s anomalies and maintenances occurred because of the test devices and their environmental variables. Data coming from medical devices and IoT Plug-ins which are connected to device to sense ambient factors of environment is recorded in knowledge base of LabHub by defining as triples according to MTDO. By this way, the required information can be queried by SPARQL whereas by using inferencing capability of semantic web, new information can be added to knowledge base.

The methodology used to develop the MTDO is based on the “Ontology Development 101: Guide to Building Your First Ontology”, adding an innovative and comparative approach to ontological identification of different medical devices. The ontology development team consists of two ontology engineers and a domain expert. Protégé [40] is used as an ontology development environment and OWL syntax [41] is preferred as ontology development language.

Since the medical laboratory is divided into sub-domains within itself, clinical biochemistry laboratories, as one of sub-laboratories where a lot of medical test analysis are requested by physicians, have been chosen as the use case. In the first draft, the steps specified in the "Ontology Development 101: Guide to Creating Your First Ontology" were completed, and concepts and relationships between these concepts were defined as “Entities” and “Object Properties” respectively in order to describe the anomalies of a medical laboratory that may occur depending on the device and the environment of the device. Fig. 2 shows some main concepts and object properties of MTDO first draft.



Fig 2. The main concepts of MTDO first draft.

For example, “PreAnalyticPhaseAnomaly” “isCausedDuring” “MedicalTest” is illustrated and defined as in Fig. 3.

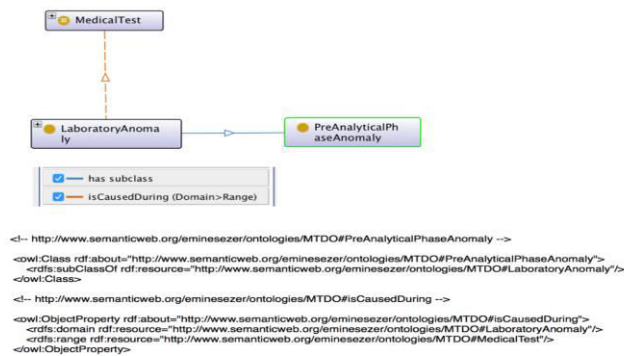


Fig 3. "isCausedDuring" object property definition.

In the next process, "MedicalDevice" concept is focused on to define its properties and relations to be able to define anomalies with data-awareness. Two devices developed by two different manufacturers Siemens Advia 1800 Chemistry Analyzer and Beckman Coulter AU680 Chemistry System, which are used as chemical system for analyzing the same medical tests were selected to describe ontologically. After the technical properties affecting the working status of the device are defined as data properties, the environment variables affecting the operation of the device are defined as sub-properties of "environmentVariables" data property of IoLT Plug-in. The working conditions of Advia1800 is initialized, also. For example, operating temperature range for Advia1800 is determined as 18-300C is defined by "workingTemperature" data property of Advia1800 concept where the environment temperature is defined by "ambientTemperature" data property of IoLT Plug-in as illustrated in Fig. 4.



Fig 4. Defining environmental variables as data properties.

The same procedure is performed for AU680. Additionally, a meta-concept named "ChemistryAnalyzer" is created and concepts and data properties common to AU680 and Advia1800 have been moved to the "ChemistryAnalyzer" concept. "IoLTPlugIn" concept that is common for AU680 and Advia1800 is also added as core concept in meta-ontology. When the ontology development is finished for these two device, only one ontology is stand for knowledge base. The common entities with their data properties and object properties construct the core concepts while the specific concepts, object properties, and data properties are customized for each medical device. The last draft of MTDO's core concepts are shown in Fig. 5.

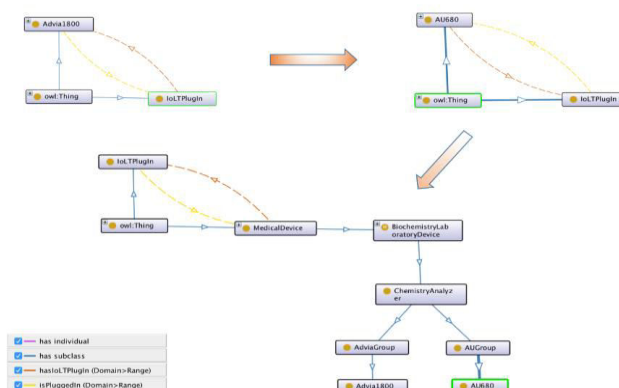


Fig 5. Core concepts: "IoLTPlugIn" concept and "MedicalDevice" concept

As a summary, an iterative entity description process is realized to define core concepts for medical devices. To describe any new medical device according to the ontology, the properties and relations would be inherited from core concept while technical conditions for device to work properly and accurately would be customized individually. Big data-aware ontology development process reformed in this study is focused on the describing “MedicalDevice” concept and illustrated in Fig. 6. Deciding any term if it exists in core “MedicalDevice” concept or sub-concept is the key point for data awareness.

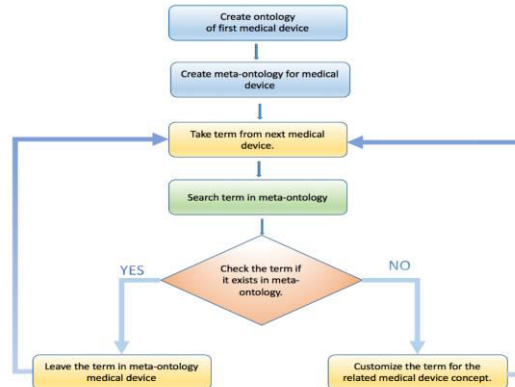


Fig 6. Iterative meta-ontology development process

IV. RESULTS

LabHub is developed as a smart medical laboratory information system that can detect anomalies in the test values analyzed and produced by test devices due to the inappropriate environment variables or human faults in medical laboratories and can also make suggestions for maintenance such as kit replacement, device calibration, and etc. The stakeholders of LabHub can be anybody or institutions like healthcare organization, healthcare professionals or private medical laboratories. LabHub architecture is designed as a cloud platform that directs the requests from the client to the data and services reserved for them through a presentation layer which is implemented as multi-tenant application model.

The Medical Laboratory Monitoring Service collects any required data for the devices and also from the environment the device located through IoLT (Internet of Laboratory Thing) plug-in so that the corresponding device produces an effective and accurate result. IoLT plug-in can be plugged on any medical test device regardless of the brand, the software on the device and of the which laboratory used. The data sense by IoLT plug-in is transmitted to the Cloud Based Big Data Management Platform. These data are described, defined and processed according to the Medical Test Device (MDTO) Ontology to be processed by Anomaly Detection Service and Preventive Maintenance Server.

MTDO is developed by using a big data-aware ontology development methodology which is explained in this article. The existence of different devices with different and various working conditions, MTDO has to be propose a flexible structure to extend for each laboratory. By defining a meta-concept for medical devices which inherits its data properties for individual technical specifications ensure the reusability and flexibility required.

This methodology can be used not only for medical test devices but also for defining ontologies that define different devices or concepts used for the same application in the same domain. An example of this is an ontology that will be developed to monitor land vehicles in the vehicle fleet and follow up the vehicles’ maintenance processes.

V. CONCLUSION AND FUTURE WORK

The management of anomaly monitoring and control, which is necessary at every stage for an accurate and reliable result, should be suitable to be carried out from a single location, especially in high-volume laboratories, allowing rapid intervention. Anomalies should be determined by monitoring internationally accepted quality and/or performance indicators with the same process LabHub, an intelligent and big data-aware LIMS system, provides anomaly detection and preventive maintenance services for medical laboratories in a health institution to detect analytical errors and/or to prevent these errors by using machine learning algorithms. The architecture of LabHub is based on IoT technologies, big data, semantic web, machine learning and cloud computing. LabHub is a unique LIMS system in terms of the services it offers and the technologies it uses for these services. It can be considered as an add-on to LIMS where the laboratory analysis processes where the sample is taken and the result is produced.

The analytical anomalies can be grouped in three categories: pre-analytical phase anomalies which can be occurred due to environmental variables such as ambient temperature, ambient humidity and etc., analytical phase anomalies such as pipetting errors, voltage changes and etc., and post-analytical phase anomalies such as turn-around time and etc. The anomalies may be arisen due to medical device as well as the environment conditions where the medical device is located.

Taking into consideration that a medical laboratory can consist of different devices which have different working conditions, MTDO is developed to describe structured and unstructured data by defining semantically. For this purpose, a data-aware ontology development process, which is used to develop MTDO that is building block of the knowledge base of LabHub, is proposed in this study.

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