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MediXcel Security and Compliance FAQs

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CONFIDENTIAL

Revision History

Revision	Date	Reason for Change	Author
0.1.0	09-07-2015	Initial Draft	Aditya Patkar
0.2.0	23-03-2016	Updated Draft with new Guidelines	Kishan Gor
0.3.0	28-04-2017	Updated Draft after MOH India release	Aditya Patkar
0.4.0	15-09-2017	Updated Draft after Security Review	Ajay Mandera
0.5.0	26-03-2018	Updated Draft after Security Review	Aditya Patkar
0.6.0	30-04-2019	Updated Draft after HIPAA Review	Aditya Patkar
0.7.0	05-06-2019	Updated Draft after GDPR Review	Ajay Mandera
0.8.0	09-09-2020	Updated Draft after Internal Security Review	Aditya Patkar
0.9.0	01-02-2021	Updated Draft - general review	Ajay Mandera
1.0.0	10-05-2021	Updated Draft after ABDM Review	Kishan Gor
1.0.1	25-12-2021	Updated Draft after ABDM Compliance	Aditya Patkar
1.0.2	15-01-2022	Updated Draft after Security Review	Aditya Patkar
1.0.3	15-04-2022	Updated Draft after Security Review	Ajay Mandera

NOTES:

1. Revision Rules:

- Decimal revisions (0.x, x.x) indicate work-in-progress 0.1, 0.2, 0.3, …x.2…x.9..
- Integer revisions (x.0) indicate an approved baseline document: 1.0, 2.0, 3.0, x.0.
- Alpha revisions (A, B, C etc.) can be used for non-I/A documents.

2. The File Properties REQUIRING update prior to check-in are:

Summary Properties

- Subject Document Title (Description with Type)
- Version No. Version No. Pertaining to this document
- Comments Document Revision Level (0.1, 0.2, 1.1, 1.2, etc)
-

Custom Properties

- Owner Project Manager (eName)
- Document Code Identification Code (Auth No – Country Code City Code – Division Code – Doc Type – Revision No)
- Meta Code Internal Filing Code
- Document No. Document number and revision level (e.g. 10022_1v0, 10088_0v2, etc)
- Tags Keywords to identify this document

3. Project teams can add Main section or sub sections and even Appendices if required. In no case should the main sections defined in the current template should be deleted. Do not delete inapplicable sections from this document. Instead, indicate it is not applicable or NA

Table of Contents

Definitions and Abbreviations

Abbreviation or Acronym	Definition
LIMS	Lab Information and Management System
HIMS	Hospital Information and Management System
HIS	Hospital Information System
SMS	Short Messaging Service – Used in Mobile Phone to Message
HIPAA	Health Insurance Portability and Accountability Act of 1996
NABH	National Accreditation Board for Hospitals
CPT	CPT (Current Procedural Terminology) codes are numbers assigned to every task and service a medical practitioner may provide to a patient including medical, surgical and diagnostic services
ICD -10	International Coding Directory: Directory used to allocate codes to all diseases and medical conditions. 10 standards for the latest version to be released
EHR	Electronic health records
OPD	Out Patient Department – Patients come for a visit and leave within 24 hours maximum
IPD	In Patient Department – Patient is admitted into the hospital and kept in a room/bed for over 24 hours
LAN	Local Area Network
LOINC	Logical Observation Identifiers Names and Codes (LOINC) is a database and universal standard for identifying medical laboratory observation
SNOMED-CT	SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms) is a standardized, multilingual vocabulary of clinical terminology that is used by physicians and other health care providers for the electronic exchange of clinical health information.
PHR	Patient Health Records

Abbreviation or Acronym	Definition
EMR	Electronic Medical Records
ABDM	Ayushman Bharat Digital Mission
NHA	National Health Authority

About Plus91

Plus91 Technologies is a Healthcare Technology Company. We create and implement Electronic Medical Records, Laboratory and Hospital Information Management Systems, Disease Management Systems, Disease Surveillance Systems and Healthcare Analytics products. Our products are used a Clinics, Labs, Hospitals and Wellness Organizations. We sell directly to Private organizations as well as do state and nationwide rollouts for Ministries and NGO's.

We strategize and manage Digital Marketing Solutions for Healthcare Providers and Healthcare value chain stakeholders.

Plus91 has for over 12 years built Healthcare IT Products and Projects and supported Digital Marketing Services. Our core-team of technology consultants, developers, testers, project managers and designers have extensive experience in understanding Healthcare requirements and mapping them to technology paradigms.

Plus91 and its Leadership is considered influential in the Digital Health IT space and is seen as a leading innovator internationally. We have been active in India, Middle East, Africa and the United States. We love to collaborate with local stakeholders and improve healthcare delivery systems all over the world.

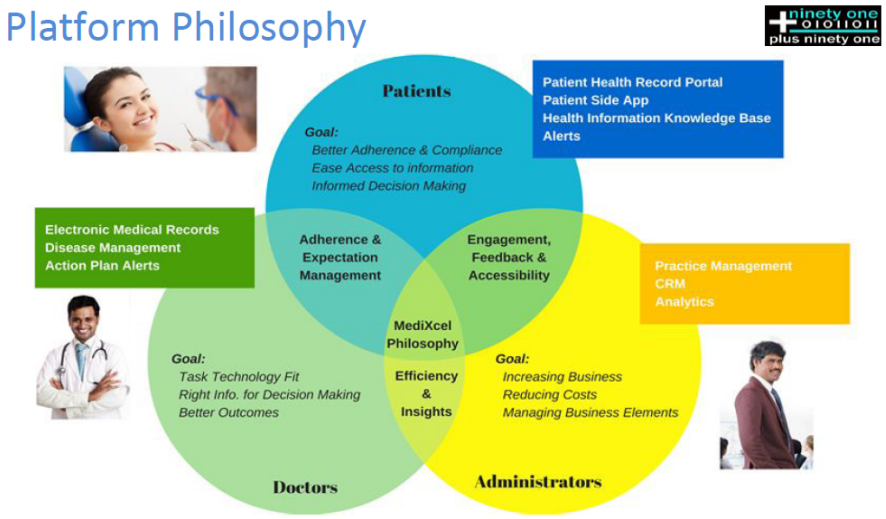


Figure 1: MediXcel - Platform Philosophy

MARQUEE CLIENTS

- HealthConnect - Sierra Leone
- Ministry of Health - Ghana
- ResearchDX, Irvine – USA
- Perkin Elmer Genomics - USA, India, Sweden
- KEM Hospital, Mumbai - India
- Jhankaria Imaging Center, Mumbai - India
- Mpowerminds Clinics India (By Aditya Birla Group),Mumbai - India
- Malpani Infertility Center, Mumbai - India

About MediXcel

MediXcel is a flexible software solution for clinics, polyclinics, clinic chains, diagnostic centers, pathology & genetic labs, health networks and hospitals along with Governments and NGOs . It manages Medical Data of the patients and Administrative data of the setup(s) and provide analytics and patient engagement solutions. Its design lets user store data with ease, quickly retrieve data and use this data in various combinations and formats to make better decisions on patient treatment, customer service and practice profitability.

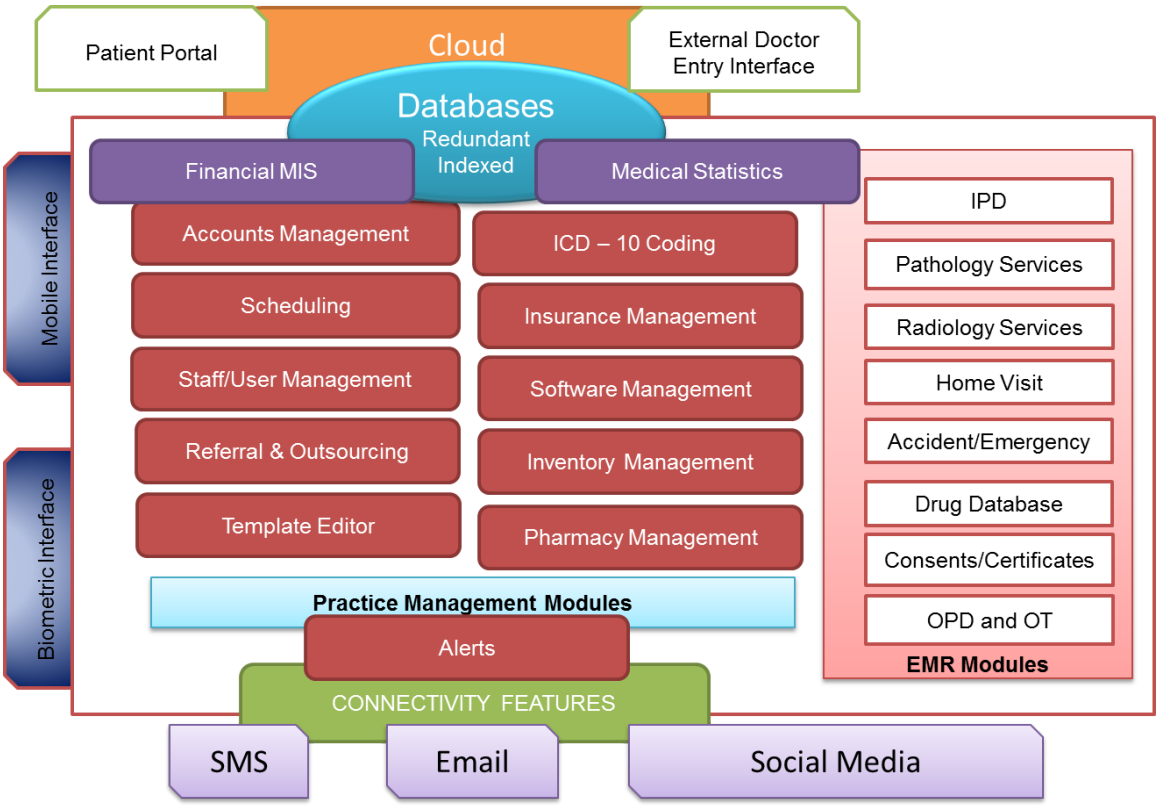


Figure 2: Functional Diagram of MediXcel Platform

Some of the key areas we have identified where the MediXcel software operates are:

a. Billing and Accounting Reports
b. Appointment Management and Work Order management
c. Electronic Medical Records and Reports with a Single Record
d. MIS Reports
e. Software Management
f. Individual Partner Clinic or Lab – Rate / User/ Timing / Appointment management

g. Patient Portal (View Records / Appointments / Request Appointment / See Videos / Provide Testimonial)
h. Multi Clinic / Lab Management and Multi Clinic / Lab MIS
i. E-mail and SMS Alerts
j. Internal Staff Messaging
k. Lab Referrals and Access to Labs and more….

Product Scope

The Product scope is continously being updated. Hence please contact us for the later high level feature list. This is an indicative list

1. Administration

a. Appointment Scheduling / Work Order Creation for Walk-ins or Collection Centre based Work Orders
    i. By Service / Doctor/Modality
    ii. Multiple Services in a single schedule with option to block multiple timeslots for longer procedures
    iii. Option to cancel / update appointment
    iv. Confirmation SMS / E-mails sent on setup
    v. Online Appointment Booking option via Patient portal (future via website)
    vi. Search by Mobile Number option or UID along with Name
    vii. Lab or Department Based Access / Complete Access based on Receptionist desk access control
    viii. Collection Centre or Ordering Physician / Hospital based access to add Work Orders
    ix. Sample Collection and Despatch
    x. Home Collection option

b. Billing
    i. Bill is generated at the bottom automatically for given schedule with option to update based on activity done at chair
    ii. Add / Update Tax / Discount in Bill
    iii. Add / Update non-service items in Bill (E.g. Films, etc)
    iv. Select between multiple billing rates (Normal / Loyalty Card Holder) or based on channel / channel partner rate
    v. Capture payments from patient / insurer with mode of payment and payment details with Option to add multiple payments over time
    vi. Add Bill stand-alone from an appointment for a given patient
    vii. See Ledger between 2 dates with export to Excel option
    viii. Manage and Update your internal service and rate list

ix. Add Referring Network / Doctor (Super Referrer) with fees per service as amount / % and generate monthly report of amount owed
x. Add Channel and Channel Partners with fees per service as amount / % and generate monthly report of amount owed
xi. Unpaid Bills listing and reminders
xii. Add / Update Outsource Lab with rates paid to them. Track Outstanding to the lab.
xiii. IPD Billing
xiv. Pharmacy Billing

c. User Management with Access Control
    i. By User Type or Actual user
    ii. Read / Write / View options
    iii. User Management across desks and locations
d. Inventory Management
    i. Masters:
    ii. Mapping for Auto-Debit of Product from department/central stock to Service
    iii. Create and Track Purchase Orders
    iv. Accept Partial and Complete delivery and track status with Batch Nos / Expiry with option to reject delivery
    v. Usage from main stock level:
    vi. Department Management:
    vii. Assignment of Inventory to User
    viii. Reports for all transactions based above
    ix. Expiry Management
    x. Threshold based alerts
    xi. First in First out flow with option to edit batch no used
e. E-mail and SMS Integration for alerts and reminders and mass E-mail / SMS setup with Tags
f. Service Management - Name / Requirement / Connection with Template Editor / Rates / Location Available / Default Inventory Auto-Debit
g. Referral Tracking for Referrers and Super Referrers
h. Internal messaging between users
i. System generated alert notifications for staff based on Staff Group
j. Audit Trail and Login Instances tracking
k. Collection Centre Access: Tracking Billing / Access Rights / Registers.
l. Feedback Management
m. Pharmacy Management
n. CRM
o. Lead Management: Add / Update / Convert Leads. Report on Lead conversions.
p. IPD:
    a. Admin:
        i. Manage Rooms / Beds

ii. Manage Billing Categories
iii. Manage OT
iv. Manage IPD Services
v. Manage IPD Staff Schedule
vi. Manage Surgeries and Packages

b. Admissions, Transfer and Discharge
c. Operation timings and OT Bookings
d. MIS:
    i. Admission Register
    ii. Discharge Register
    iii. Current Hospital IPD Patient Register
    iv. IPD Billing Report
    v. IPD Payment Report
    vi. Refund Report
    vii. OT Bookings Register and more.

2. EMR + LIMS + RIS

a. Service Based Templates (Consult / Procedure / Service)
    i. Consult/Procedure/Imaging Tests:
        i. Consultation Templates
            1. History Section for each template to capture general information – filled by Support Staff or Patient on Tablet
            2. Symptoms / Observations by Section
            3. Prescription Pad
            4. Recommendation pad
            5. Lab Test Request pad
            6. Add Tags to Patient
            7. ICD 10 coding engine with each template
            8. Specialized templates for:
                a. Gynaecology
                b. Obstetrics
                c. IVF
                d. Sperm Processing
        ii. Lab Testing:
            1. Sample Acceptance and Rejection
            2. Report Upload and Parameter wise entry option
            3. Parameter Creation with variable Reference Ranges
            4. Multi-level verification system
            5. Graphical tracking of values
            6. Print / E-mail Report options
            7. Selection of content within template by multiple template options added for service
        iii. Word based editor to add notes

iv. Attach Digital Signatures of Doctors by Doctor Login / Super admin login
v. Attach Multiple Images (Auto Image attachment for digital equipment if APIs available) / PDF to each report

b. Template Editor
    i. Edit Default Templates content under Management for given service including multiple report formats
    ii. Edit Reference Range with Gender and Age based highlights / Sample information under Lab Templates
c. Single Patient Record View -> History with each event / visit with search by Name / Loyalty Card Number / Patient Id / Mobile Number / Tags
d. Future Recommendation options to follow – up with alerts setup for staff / patient
e. E-mail Report to Ordering Physician / Patient
f. MIS Reports based on Service / Results (For Structured Data where possible)
g. IPD:
    a. Daily Vitals, Fluid Monitoring and Doctor Notes
    b. Lab Request Pad
    c. Discharge Card Generation
    d. Operation Notes
    e. Nursing Station
    f. Maternity

3. Patient Portal

a. Set Appointments and see upcoming / previous appointments
b. Access Reports
c. Upload External Reports which can be seen by Doctor
d. See bills and make payments online (optional)
e. See push notifications
f. See Alerts set by Staff or for future check-ups

Certifications

1. ABDM Certificate

national health authority

ABHISHEK KUMAR, IRS
Director (IT)

सत्यमेव जयते

भारत सरकार
Government of India
राष्ट्रीय स्वास्थ्य प्राधिकरण
National Health Authority

Date: 29/12/2021

To,

Sh. Aditya Patkar
Chief Executive Officer
Plus91 Technologies Private Limited
601/A, East Court, Next to Phoenix Market City,
Off, Nagar Rd, Viman Nagar, Pune,
Maharashtra 411014, India
Client ID - PTPL_162698

Subject: Integration with ABDM- reg.

We appreciate the participation of your organisation in the Sandbox of Ayushman Bharat Digital Mission (ABDM). We are glad to inform you that your solution/product 'MediXcel' is now integrated with ABDM for the following capabilities: -

1. Health ID creation and capture & verification for seamless patient registration
2. Building Health Information Provider (HIP) services to share digital records via Personal Health Records (PHR) app
3. Developing Health Information User (HIU) services to provide view of patient's medical history to authorized healthcare workers with complete consent

Please note that this letter signifies the success of initial integration. This letter does not validate the compliance to the changes that must be regularly and promptly incorporated.
You may use the "ABDM-integrated" logo on those modules of your product which have been integrated with ABDM.

Yours sincerely,

(Abhishek Kumar, IRS)
Director-IT
Ayushman Bharat Digital Mission
National Health Authority

Disclaimer: Please note that this letter of integration reflects achievement of a milestone in the integration process with ABDM. Unless otherwise expressly agreed in writing, National Health Authority, ABDM and its affiliates (collectively "ABDM") are not in any way associated with the Integrated Organisation or responsible or liable for the goods and services offered by them or for anything in connection with such integrated organisation. ABDM does not endorse or approve and makes no warranties, certifications, approval, authorisation, representations or undertakings relating to the content published in public domain by the Integrated Organisation. The purpose of this letter is only to confirm the fact that the product whose integration was initiated has now been successfully integrated.

3rd & 4th, 7th & 9th Floor, Tower-I, Jeevan Bharati Building, Connaught Place, New Delhi-110001
Tel.: 011-2346 8820, Email : ed.it@nha.gov.in Website: www.ndhm.gov.in, www.pmjay.gov.in

2. OWASP Security Certificate

astra

CERTIFICATE OF CYBER SECURITY AUDIT

THIS CERTIFIES THAT

MediXcel EMR / HIS

by Plus91 has successfully passed the in-depth security audit & pentest by remediating the found vulnerabilities

CERTIFICATE ID: 6fbd6bbc-bde8-4f7d-a432-979e25800550

(Verify certificate here)

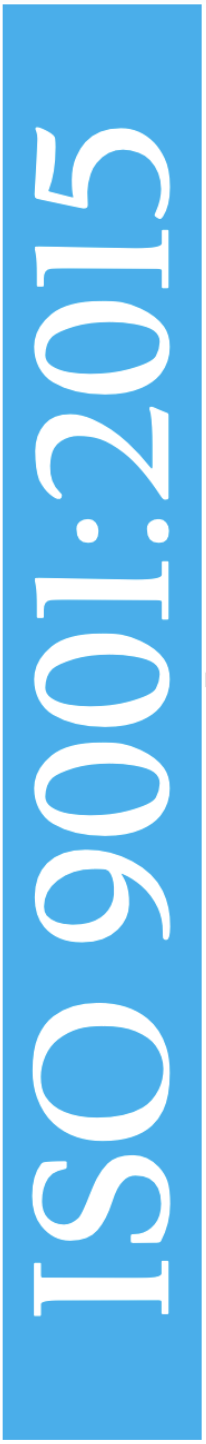
Jan 12, 2022 — Issued on

Jan 12, 2023 — Valid till

Ananda Krishna

CTO, Astra Security

3. ISO 9001:2015



HMC

Certificate of Registration

Hive Mind Certification hereby certifies that the Quality Management System of:

PLUS91 TECHNOLOGIES PRIVATE LIMITED

601 A, EAST COURT PHOENIX MARKET CITY, VIMAN NAGAR, PUNE- 411014

has been assessed and found to operate in compliance and meets the requirement of following standard's

ISO 9001:2015

For the scope of

HEALTHCARE AND IT SERVICES

Initial Date of certification	:	JAN.28.2022
Current date of certification	:	JAN.28.2022
Date of expiry	:	JAN.27.2025
1st Surveillance	:	DEC:2023
2nd Surveillance	:	DEC:2024
Certificate Number	:	QMS-XX-XV-I-IX-2312
NACE Code	:	T.97

Hive Mind Certification

Authorised Signatory

HMC-BAR QMS ACCREDITED USA

ISO 9001 Registered

For any query mail us at contact@hmcertification.com

https://hmcertification.com

This certificate is the property of HMC-BAR and Hive Mind Certification. This certificate is valid for three years from the date if issuance. In case of withdrawal, the certificate must be returned to Hive Mind Certification or HMC-BAR. Registration No. - HMC-BAR - 2705001-1

4. ISO 27001

ISO 27001:2013

HMC

Certificate of Registration

Hive Mind Certification Hereby certifies that the Information Security Management System of:

PLUS91 TECHNOLOGIES PRIVATE LIMITED

601 A, EAST COURT PHOENIX MARKET CITY, VIMAN NAGAR, PUNE- 411014

has been assessed and found to operate in compliance and meets the requirement of following standard

ISO 27001:2013

For the scope of

HEALTHCARE AND IT SERVICES

Issue Date of certification	:	JAN.28.2022
Date of expiry	:	JAN.27.2025
Certificate Number	:	ISMS-XX-XVII-VIII-1018
NACE Code	:	T.97

Hive Mind Certification

Authorised Signatory

HMC-BAR QMS ACCREDITED USA

HMC ISO 27001 Registered Hive Mind Certification

For any query mail us at contact@hmcertification.com

https://hmcertification.com

This certificate is the property of HMC-BAR and Hive Mind Certification. This certificate is valid for three years from the date if issuance. In case of withdrawal, the certificate must be returned to Hive Mind Certification or HMC-BAR. Registration No. - HMC-BAR - 2705001-1

5. CMMI Level 5

CERTIFICATE

PARAMOUNT QUALITY CERTIFICATIONS

Scan this code with your smart phone to verify the certificate

Certificate of Compliance

This is to certify that the services provided by:

PLUS91 TECHNOLOGIES PRIVATE LIMITED

601/A, 406, PHOENIX EAST COURT, NEXT TO PHOENIX MARKET CITY,
OFF NAGAR ROAD, VIMAN NAGAR, PUNE, MAHARASHTRA - 411014, INDIA

has been independently assessed by PQC and found to comply with the requirements of

CMMI MATURITY LEVEL 5

For the following scope:

DEALS IN HEALTHCARE & IT SERVICES.

Certification Calendar:

Client Id: 8012

Certificate No: INCMMI/MH-8779/0222

Initial Registered Date: 02.02.2022 Issuance Date: 02.02.2022

Date of Expiry: 01.02.2025

1st Surv. Due: 01.02.2023 2nd Surv. Due: 01.02.2024

CMMI Level 5 CMMI LEVEL - 5 CERTIFIED

Authorized Signatory

PQC SCT

ABDM - Ayushman Bharat Digital Mission FAQs

MediXcel is now an ABDM Certified HMIS / EMR / LIS solution provider. The first full suite private vendor HMIS to have gotten certified.

You can see details about the certification here: https://abdm.gov.in/home/partners

MediXcel is now integrated with ABDM for the following capabilities:

1. Health ID creation and capture & verification for seamless patient registration.

2. Building Health Information Provider (HIP) services to share digital records via Personal Health Records (PHR) app.

3. Developing Health Information User (HIU) services to provide a view of a patient's medical history to authorized healthcare workers with complete consent.

Security FAQs

Sr. No	Category	Questions	Answers
1	Services/Operations	Browsers and all the versions supported?	We support only Google Chrome all versions. We upgrade every 6 months to also support Mozilla Firefox, Opera and Safari.
2	Services/Operations	Does it requires installation of any plug-ins or other software to operate correctly?	No, none on the side of User. Server side environment to be setup (Apache / MySQL / PHP and their extensions)
3	Services/Operations	Is hardware dependent (Mac, Android, Windows etc)?	No
4	Services/Operations	Is it possible to build new screens or modules not provided by default?	Yes
5	Services/Operations	How do you monitor the software running on your production systems?	We use AWS (Amazon) tools to monitor Server performance. Alerts via e-mail are setup for thresholds being crossed for Server / bandwidth Alerts via e-mail are setup via error log for any PHP / Apache errors causing product to fail
6	Services/Operations	What kind of Disaster Recovery /Business Continunity Planning is in place?	We offer a weekly back-up service of the database as part of the base setup Additional options: Daily Back-up of Database Real time Back-up of Database Real time syncing of package and database on a remote server of your choice (Which can be used for BCP)
7	Services/Operations	Which disaster recovery capability are available (export to a remote site, to a customer site)?	We can have a real time syncing of Software and Database to a remote site. To be used only if

			main site is down for longer then a specified threshold.
8	Services/Operations	How often DR/BCP is tested?	Once in 6 months
9	Services/Operations	What is the hotline and support process?	Hotline number is provided - working 6 days a week / 9am to 9pm. Support process has been highlighted in separate document already shared.
10	Services/Operations	What are opening hours?	Office Open hours: 9 am Support requests will be monitored from 7am
11	Services/Operations	Which languages are supported?	English / Hindi / Marathi
12	Services/Operations	Can customer contact the hotline to get information on planned maintenance?	Yes
13	Services/Operations	Is tech support handled by the you or outsourced?	Handled by Plus91
14	Services/Operations	How do you notify about interruptions or downtime, including scheduled maintenance?	Via E-mail to all concerned stakeholders. We also show a message on the same in App to all login users 48 hours prior if this step is allowed by the client
15	Services/Operations	How do you resolve respond to slowness or other performance issues?	Server Sanitation Check Back-up and purging of non-essential logs Query Log times checked to see if specific queries taking time and fixed on an individual basis if needed
16	Services/Operations	Will we get notice of major updates of the service?	Yes
17	Services/Operations	What all usage, performance, audit or other reports will be shared with IS?	Monthly Report on Server Performance / Bandwidth Used will be shared. Login Instances and Product Usage statistics are available in the application itself
18	Services/Operations	Are there any maximum number of simultaneous connections	No
19	Services/Operations	Are ther maximum transferred volume of data?	No, it will vary based on your AWS instance and will be charged beyond threshold
20	Services/Operations	What is maximum available network bandwidth?	It will depend on the AWS instance we select, it will be updated as needed during peak times or heavy volume days
21	Services/Operations	When these limitations are reached, will there be any additional costs apply?	Yes. If we have to update the AWS instance to a larger one, differential costs will be applicable
22	Services/Operations	What is your data backup and restore policy? (retention, frequency, online/offline mode)?	It will be built with the Client. We take by default a weekly data back-up. Frequent options are available including real time offline sync for BCP
23	Services/Operations	How back up is triggered (manual, automated, self-service)?	Automated
24	Services/Operations	How restore process is managed (manual, self service)?	Manual
25	Services/Operations	What is response time for a restore request?	2 hours minimum to 24 hours maximum
26	Services/Operations	What is the delay to obtain more performance?	2 hours minimum to 24 hours maximum
27	Services/Operations	What is the additional cost (if any)?	NA - depends on usage / bandwidth being consumed at the time

28	Services/Operations	What is your uptime/ Availibility?	Server Uptime - 99.95%
29	Services/Operations	What is planned downtime allowed per year?	We ideally like to keep this down to 48 hours in the year (done on weekends or holidays)
30	Integration	How will the SaaS application integrate with the other software we use? (Like Active Directory, OKTA, Tally, etc)	We will use REST APIs where possible. For Medical data we may use HL7 based on LOINC or Snomed CT codes
31	Integration	What are the limitations for interfaces?	None, we are open to trying all sorts of integration and interfacing
32	Security/Privacy	What sort of security tests do you perform before a software release?	We ensure all general HIPAA guideliness are followed (unless specifically over ruled by the client) We ensure SSL encryption is setup if the certificate is provided by client We do stress and load testing of the server and application
33	Security/Privacy	What is data isolation policy?	We can provide for Firewall, Domain or Server Isolation (using specific Ips) if the client is requiring such a setup
34	Security/Privacy	Do you use code you didn't write?	We do use Open Source Libraries which are tested and reviewed for any known bugs
35	Security/Privacy	How do you know the code is secure?	We have a dedicated testing team which ensures the code is secure. We also do an Annual VAPT certification from a 3rd party. We also do code check for each release using SonarQube
36	Security/Privacy	Before roll out into production, are there some intrusion tests performed ?	Basic Access Rights testing is performed If specific Isolation policies are in place then they are also tested
37	Security/Privacy	Who will have access to client data?	Dedicated member of Support team will have access at times to help specific queries.
38	Security/Privacy	What are the 3rd party partners and subcontractors involved (if any)?	None
39	Security/Privacy	Are there any subcontractors/partners for underlying hosting services (mainly for PaaS & SaaS)? What are related SLAs?	Amazon AWS - https://aws.amazon.com/ec2/sla/
40	Security/Privacy	Are there any subcontractors/partners for underlying platform services (mainly for SaaS)? What are related SLAs?	None
41	Security/Privacy	Are there software suites/components from other suppliers (e.g. to be considered for license management, for security assessments, ...)?	SSL Certificate For any specific Add-ons requested by the client not part of the core product. E.g. Iphone App development
42	Security/Privacy	Are there firewalls in use for both internal and external connections?	Yes
43	Security/Privacy	Do you give programmers security training?	Yes
44	Security/Privacy	Do you secure your IS assets (Physically and logically)	Yes
45	Security/Privacy	How will confidential information be handled?	We will sign a NDA as part of the Agreement which covers all employees. All confidential information will be handled by 2-3 designated people in our team which will be notified to the client. All confidential information not needed beyond its use will be destroyed from our systems
46	Security/Privacy	Do use Secure Socket Layer (SSL) or other security measures?	Yes enabling a SSL (TLS standard) certificate is an option we provide. Client needs to purchase said certificate

47	Security/Privacy	Are there policies and procedures in place for security breaches, data theft, privacy and other concerns?	Yes
48	Security/Privacy	Are data flows encrypted ?between the customer and the SaaS Application?	Yes enabling a SSL certificate is an option we provide. Client needs to purchase said certificate
49	Security/Privacy	Are all copies (e.g. backup, archive) encrypted also?	All Amazon AWS instances with Data are encrypted even at Rest (AES). Any local storage done by client is not under our purview
50	Security/Privacy	Which security policies / procedures are implemented?	• Authentication • Roles and Authorization / Access Control Granularity including Password hashing • Auditing / Logging • Vendor Monitoring, Reporting, and Alerting • Business Continuity and Back-up • Data Security / Data Loss Prevention • Integrations and APIs
51	Security/Privacy	How do you ensure your servers are up to date with security patches?	We do a check every month and install or update the required patches
52	Security/Privacy	Have you addressed the confidentiality, data privacy and security topics, in accordance with India and state laws?	Yes
53	Security/Privacy	Who will own the data and who has right of use it?	Client or Patient depending on the governing laws of the country
54	Security/Privacy	Are Sessions IDs managed to ensure no penetration or hijacking is possible?	Yes, session identifiers are rotated at each login and also tied to the browser and IP address.
55	Security/Privacy	Do you have a data deletion policy?	Yes, we do have a data deletion policy. It mirrors the HIPAA guidelines but can be followed based on your local country guidelines if needed.
56	Audit	What can be audited?	Server Performance - Provided monthly Bandwidth Usage - Provided monthly Application Usage / Login - from within application

Meaningful Use Compliance FAQs

MediXcel benefits its clients by ensuring that Meaningful Use guidelines are met in accordance with the most comprehensive rules provided on EMR and EMR data management in the world to ensure Patients are benefitted from their own data.

Sr. No	Meaningful Use Objective	Module	Description in MediXcel

1	Use Computer Provider Order Entry	EMR – Consults / Labs / USG	Add Patient Medical Records which can store Medication details, Lab Details, Therapies. Also add images and external reports Multiple templates can be added to cover additional points as per requirement. All records can be stored, retrieved and managed
2	Implement drug/allergy checks	Drug Manager	Add and Edit Drug Master List. Create Allergy and Drug Interaction pointers which alert you in case of clashes User defined Drug to Drug rules SMS alerts for Medication reminders
3	Maintain an up-to-date problem list of current and active diagnose based on ICD-10-CM or SNOMED CT®	EMR – Consults / Labs / USG	ICD 10 coding available for diagnosis SNOMED-CT lists can be enabled for Diagnosis or Test /Service Mapping if needed
4	Record and chart changes in vital signs	EMR – Consults / Labs / USG	Add vital signs for each visit Modify template to include vital signs of your preference Clinical Decision support using user created pop-ups and tips Graphical representation of certain vital signs Auto Calculation of BMI etc
5	Record smoking status for patients 13 years old or older	EMR – Consults / Labs / USG	Smoking, Alcohol and Family/Personal History can be captured Retrieve all patients matching certain fixed history criteria, free to choose and mix and match criteria
6	Incorporate clinical lab-test results into EHR as structured data	EMR – Consults / Labs / USG	Add Lab Data into structured formats of choice Out of Range alerts Scan and attach external reports Interface with online Lab Transfer system possible Graphs and Statistics on various parameters possible on each patient or whole data set
7	Generate lists of patients by specific conditions	Patient Record Manager	Clinical Information Based Stats Use multiple parameters using OR and AND formulaes Output is a full List of patient matching criteria and also the total number
8	Report ambulatory quality measures to CMS or the States (Eligible Physicians only)	MIS Reports - CPH	Create a unqiue graphical dashboard on a whole range data and terms
9	Send reminders to patients for preventive/follow-up care	Alerts	SMS and Email Alerts are integrated for Follow Up visits, Medication Reminders, Report Reminders. Also IVRS integrated with MediXcel to take and record calls
10	Implement ve clinical decision support rules relevant to specialty or high clinical priority	Tool Tips and Clinical Support	Generate User Based Clinical Decision tips within the software Easy access to these tips on roll over Alerts created when reference ranges are crossed. Manual alerts can be created as a display, SMS or Email to concerned person
11	Provide patients with an electronic copy of their health information upon request	Email Plugin, Online PHR Access	Print on Letter Head or with Letter Head Visit Report, Patient History Summary, Prescription, Referral Letter etc Printout of entire records of fixed bits is possible Allow to email anything which can be printed.
12	Provide patients with electronic access to their health information within 96 hours of the information being available (EP only)	Online PHR Access	Allow Patients to access their information on a patient portal online Integrate portal into your website Create a whole new patient portal website for your practice Online-Offline mode to continously detect internet and update data

13	Provide clinical summaries to patients for each visit. (EP only)	EMR – Consults / Labs / USG	All Patient Information can be selected and given to patient via: Email, Print, Patient Portal Easy to use UI allows this in one click
14	Exchange key clinical information among providers of care and patient authorized entities electronically and provide summary care record	JSON / Rest based APIs	Information can be provided in easy to use XML formats to all 3rd party resources to transfer and use without Patient Identifiers. We can also provide / retrieve data using JSON and REST based APIs
15	Perform medication reconciliation at relevant encounters and each transition of care and referral	Drug Manager	Prepare easy to use Prescription Templates which can easily be added during the visit Provide instructional, side effects data with each medication Create Medical Bills which auto deduct from inventory and help track medication inventory status
16	Submit electronic data to immunization registries and actual submission where required and accepted	Immunization Templates	Information can be provided in easy to use REST APIS / XML formats to all 3rd party resources to transfer and use.
17	Protect electronic health information through the implementation of appropriate technical capabilities	User Management	Assign Unique User Ids Create and Modify User Access rights for each user Password Protection Comprehensive Audit Trails SSL Encryption Auto-logout on no activity
18	Maintain active medication/allergy list	Visit Manager	View the entire Medication History of the Patient in a single click Print Select Prescriptions for reuse
19	Record demographics	Visit Manager	Record Patient Demographics Add Patient Photograph Maintain unique Patient Id per patient Add and Use more than one number Mobile No, Address and Email

21CFR Part 11 Compliance FAQs

Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES). Part 11, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records (Title 21 CFR Part 11 Section 11.1 (a)). The FDA in the USA mainly uses the given Compliance rules to manage LIMS and Lab Information System guidelines

Sr No	Category	Points	Sub Points	Provided in MediXcel

1	Source document retention	Treat electronic record as source document and retain as required under part 312, § 511.1(b)		Yes
2	(for data entered directly into computer system)	When data is transmitted from one system to another or entered directly into a remote central computer system, maintain copy in another location as defined below (check one).		
	A	At clinical site.		Yes
	B	Another location (e.g., a data storage facility).		Option is provided
	C	Produce copies contemporaneously with data entry.		Yes
	D	Preserve copies in appropriate format such as XML, PDF or hardcopy.		Option is provided
4	1 Internal Security	Access Limitations	Password-protect individual accounts.	Yes
	A		Configure computer system to require manual login and logout.	Yes
	B		Automatically limit number of failed login attempts.	Yes
	C		Automatically record unauthorized login attempts.	Yes

	D		Do not share individual account access with other users.	Yes
	E		Do not log on to system to provide access to another user.	Yes
	F		Electronically require users to change their passwords at regular intervals.	Yes
	G		Automatically password protect computer systems when idle for short periods.	Yes
	H		Automatically log users off computer systems when idle for long periods.	Yes
	2A	Audit Trail	Keep track of all creations, modifications, and deletions electronically.	Yes
	B		Maintain all entered data: Don't obscure original data when changes are made.	Yes
	C		Time stamp change automatically.	Yes
	D		Configure computer system to require user to record reason for change.	At specific locations only or where requested by client
	E		Automatically record identity of individual who made change.	Yes
	F		Prevent users from being able to modify or delete audit trail.	Yes
	3A	Date and Time Controls	Synchronize computer system to date and time provided by international standards setting source (e.g., http://www.time.gov/)	Yes
	B		Limit user's ability to change time.	Yes
	C		Document all date and time changes (except daylight savings time).	Yes

	D		Include year, month, day, hour, and minute in time stamp	Yes
	E		Include time zone in date and time stamp.	Yes
	F		Explain any time zone references and naming conventions in study documentation.	Yes
5	A External Security		Restrict access to computer system and data via external software applications by encrypting data as it is transferred and/or using a firewall.	Yes via SSL
	B		Maintain cumulative record that indicates names of authorized personnel, their titles, and a description of their access privileges.	Yes
	C		Prevent, detect and mitigate effects of viruses and other harmful software code.	Yes we do a Security and Virus check on Servers on a weekly basis
6	1A Other Features	Direct Entry of Data	Use prompts, flags, and other help features to encourage consistent use of terminology.	Yes
	B		Use prompts for data out of the specified range. Specify valid vs. invalid ranges and alert user.	Yes
	C		Do not set up system to enter default data if field is bypassed.	Yes
	D		You may allow system to populate field with data duplicated from another field. However, analyze potential consequences very carefully before doing so.	
	2A	Retrieving Data	Design computer system to attribute data record to each individual subject.	Yes

	3A	System Controls	Set up a full backup and recovery system to protect against data loss if records are maintained only in electronic form.	Yes
	B		Ensure that backup system maintains data integrity.	Yes
	C		Store backup records at a secure offsite facility.	Yes
	D		Maintain backup and recovery logs.	Yes
	4A	Change controls	Maintain data integrity when making changes to the computer system, such as software upgrades, security and performance patches, equipment repairs, etc.	Yes
	B		Carefully evaluate effects of any changes before and after making them.	Yes
	C		Validate changes that exceed previous operational limits.	Yes
	D		Document all computer system changes.	Yes
	5A	Training	Ensure that individuals who develop, maintain and use computer system have sufficient education, training, and experience to perform tasks.	Yes
	B		Document computer education, training, and experience of personnel.	Yes
	C		Provide training in the operation of the computer system led by qualified individuals as needed.	Yes
	D		Conduct training sessions as needed on a continuing basis in case of changes in Personnel and the computer system.	Yes

HIPAA Compliance FAQs

HIPAA Compliance ensures that the Patient Information data is not misused or shared with not essentials medical or para-medical personnel. MediXcel ensures the following guidelines are in place in the application to ensure Data Security and Compliance

Sr. No	Risks	Frequency of Controls	Control Effectiveness	MediXcel Safeguards
1	Unauthorized modification of data	Each Instance	Low	Audit Trail for each user type / user action Granular Access Control for each user type on Feature / Page / Action
2	Disclosure of confidential information (personally identifying information (PII) or health care info)	Each Instance	Significant	Access Control Rules Auto-logout Domain / IP based Access Management (optional) Option to freeze user
3	Obsolescence of systems/technology	Quarterly	Significant	Product Upgrades for new Features Product Upgrades for new Rules, Regulations and Workflow needs
4	Lack of common data definitions	Yearly	Significant	EMR allows to code or use ICD-10 for Diagnosis, LOINC for Recommendations and Test Results and SNOMED - CT for other coding Option to map between all 3 databases
5	Inability to recover from system loss or extended downtime	Semi-annually	Significant	BCP Plan in Place Basic Weekly back-up Paid plans for real-time or daily back-up options Local / Remote Site back-up option

Electronic Health Standards 2021 – India/ ISO Compliance FAQS

S. No	Category	Description	Available in Medixcel?	Notes and Remarks
			Available in Base / Optional / Partial / Not Available	Description Or Explanation of Partial or Optional
1	Patient Identifying Information	Name	Available in Base	
2		Address (all geographic subdivisions smaller than street address, and PIN code)	Available in Base	
3		All elements (except years) of dates related to an individual (including date of birth, date of death, etc.)	Available in Base	
4		Telephone, cell (mobile) phone and/or Fax numbers	Available in Base	
5		Email address	Available in Base	
6		Bank Account and/or Credit Card Number	Available in Base	We have an option to capture this while accepting payment
7		Medical record number	Available in Base	
8		Health plan beneficiary number	Available in Base	Membership Plan / Insurance Plan options
9		Certificate/license number	Available in Base	
10		Any vehicle or other any other device identifier or serial numbers	Available in Base	We have UID, family code in base and MOH, NHIA no in Ghims package.
11		PAN number	Available in Base	
12		Passport number	Not Available	
13		AADHAAR card	Available in Base	
14		Voter ID card	Available in Base	
15		Fingerprints/Biometrics	Optional	
16		Voice recordings that are non-clinical in nature	Optional	
17		Photographic images and that possibly can individually identify the person	Available in Base	
18		Any other unique identifying number, characteristic, or code	Optional	
19	HEALTH RECORD IN MOBILE DEVICES	As people become more mobile and travel becomes more accessible, patients will increasingly expect the healthcare record system to provide essential health information over mobile devices, which will give their treating clinician basic information like, medical condition, drug/allergy information etc.	Optional	Android App Optional / Accessible on Phone via Browser (PHR)
		Demographics, insurance info, medications, allergy and alerts, and vital signs are some of the records that are recommended to be provided in at least read-only manner and to the extent relevant for emergency care and quick reference. It is also possible that certain clinical (BP, temperature, glucose count) and lifestyle (steps walked, distance	Available in Base	Android App Optional / Accessible on Phone or via Browser (PHR)

		run, sleep duration and quality) related information will additionally be provided by the patient thereby providing vital clues and information on the overall wellbeing of patient.		
20	Authentication	Locally within the system the fact that a person or entity seeking access to electronic health information is indeed the one as claimed and is also authorized to access such information must be verifiable.	Available in Base	Access Control along with password based authentication
		Across the network, however extensive it might be, the fact that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information.	Available in Base	Access Control along with password based authentication
21	Automatic Log Off	An electronic session after a predetermined time of inactivity must be forcibly terminated. To log in back, the user will have to initiate a new log in session.	Available in Base	
		However, for the sake of ergonomics, it is recommended that the unsaved state of the system at the time of automatic log-off be saved and presented back to the user for further action. This should be a user-specific feature.	Optional	For specific User Types and screens on request we can enable this option
22	Access Control	The solution must assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information.	Available in Base	Every user gets a unique user id.
		In cases of emergency where access controls need to be suspended in order to save a life, authorized users (who are authorized for emergency situations) will be permitted to have unfettered access electronic health information for the duration of the emergency with the access remaining in force during the validity of the emergency situation.	Available in Base	Specific Admin Rights can be assigned to users when needed
23	Access Privileges	Ideally only clinical care providers should have access rights to a person's clinical records. However, different institutional care providers have widely varying access privileges specified that are institution-specific. No country wide standards can be specified for this at least at this point in time.	Available in Base	
		For privilege management and access control, following standards may be used: ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3) Implementation Guideline: The ISO 22600 set of standards is provided as an advisory standard for policy based access control. For the purpose of privilege management, rule / policy based access is expected to give better control and flexibility in defining and enforcing access control. Access control mechanisms such as Role Based, Policy Based, or singular user (applicable in case of mobile based PHR) are acceptable	Available in Base	ISO 22600:2014: states no other clinic or unauthorize user should be able to access the record of the patient. We dont allow any other clinc users to view the patient data unless the clinic user is authorized, 3rd clinic users to view the patient data.
24	Audit Log	Actions related to electronic health information in accordance with the standard specified in this document including viewing should be recorded.	Available in Base	
		All actions based on user-defined events must be recorded.	Available in Base	We will be updating new features into the Audit Trail as and when released
		All or a specified set of recorded audit information, upon request or at a set period of time, must be	Available in Base	

		electronically displayed or printed for user/administrative review		
		All actions related to electronic health information must be recorded with the date, time, record identification, and user identification whenever any electronic health information is created, modified (non-clinical data only), deleted (stale and non-clinical data only), or printed; and an indication of which action(s) took place must also be recorded.	Available in Base	
		A cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails should be preferably used within the system.	Available in Base	
25	Integrity	During data transit the fact that the electronic health information has not been altered in transit in accordance with the standard specified in this document must be verifiable.	Available in Base	While printing and viewing the report from PHR no data is altered. As the data content is saved same is displayed at the end.(while printing and viewing report PHR)
		Detection of events - all alterations and deletions of electronic health information should be captured in audit logs.	Available in Base	
		Appropriate verification that electronic health information has not been altered in transit shall be possible at any point in time. A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit and it is recommended that the Secure Hash Algorithm (SHA) used must be SHA-256 or higher.	Available in Base	The file is not altered. The way the file is generated and stored on the server. same file is viewed from PHR and when staff emails. Same file with same size is sent to the patient or any third party.
26	Encryption	Generally, all electronic health information must be encrypted and decrypted as necessary according to organization defined preferences in accordance with the best available encryption key strength (minimum 256-bits key).During data exchange all electronic health information must be suitably encrypted and decrypted when exchanged in accordance with an encrypted and integrity protected link.	Optional	SSL Encryption can be enabled on request by the client
		Secure Transmission standards and mechanisms must be used to allow access to health information as well as transmit data from one application / site to another. For this purpose HTTPS, SSL v3.0, and TLS v1.2 standards should be used. Please refer to relevant IETF, IEEE, ISO, and FIPS standards for same.	Optional	SSL Encryption can be enabled on request by the client
27	Digital Certificates	Use of Digital Certificates for identification and digital signing is recommended in health record system.Health record system must use following standard where digital certificates are used: ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)	Optional	Electronic Record signing using Digital Keys can be enabled on request for the client.
28	ARCHITECTURE REQUIREMENTS AND FUNCTIONAL SPECIFICATIONS	A health record system must meet architectural requirements and functional specifications to remain faithful to the needs of service delivery, be clinically valid and reliable, meet legal and ethical requirements, and support good medical practices. Therefore, a health record system must conform to the following standards:	Available in Base	Our solution has been in use since 5 years without any legal or structural complaint
		ISO 18308:2011 Health Informatics - Requirements for an Electronic Health Record Architecture	Available in Base	We confirm that up to 90% of the requirements stated in the ISO document under Structure, Process,

				Communication, Privacy and Security, Medico-legal, Ethical, Cultural and Evolution are covered in Base or optionally covered via configurations.
		ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)	Available in Base	We confirm that up to 90% of the requirements stated in the ISO document are covered in Base or optionally covered via configurations.
29	LOGICAL INFORMATION REFERENCE MODEL AND STRUCTURAL COMPOSITION	A health record system must accumulate observable data and information for all clinically relevant events and encounters. For this purpose, it is important to have common semantic and syntactic logical information model and structural composition for captured artefacts. Unless the data being captured is standardized, its communication and understanding may not be same across systems. Therefore, a health record system must conform to the following standards:		
		ISO 13940 Health Informatics - System of Concepts to Support Continuity of Care	Available in Base	All points covered
		ISO 13606 Health Informatics - Electronic Health Record Communication (Part 1 through 3)	Optional	We support HL7 / API based communication protocols
		openEHR Foundation Models Release 1.0.2	Available in Base	By and Large the foundation models are followed
		Required Model Specifications: Base Model, Reference Model, Archetype Model	NA	
		Optional Model Specifications: Service Model, Querying, Clinical Decision Support.	NA	
30	MEDICAL TERMINOLOGY AND CODING STANDARDS	In order to have semantic interoperability between different health record systems, it is necessary to follow a common terminology and coding system standards to express unambiguous meaning of data captured, stored, transmitted, and analyzed. It is also important to have these terminologies and codes in computer process-able format to aid automation and ensure that data is in an analyzable state at all times. Therefore, a health record system must conform to the following standards:		
		Primary Terminology: IHTSDO - SNOMED Clinical Terms (SNOMED CT) Implementation Guideline: A health record system must use SNOMED CT as the primary internal encoding system for all clinically relevant, including dental, nursing, substance/drugs related information. IHTSDO SNOMED CT code shall also be used while communicating clinical information to other health record systems. SNOMED CT concept codes (as pre-coordinated or as post-coordinated expressions) are to be used for all hierarchies covered under the standard unless otherwise provided in this document. It shall also be the coding system that must be used internally in other information storage and communication standards such as openEHR archetypes, HL7, DICOM, etc. IHTSDO releases SNOMED CT twice annually	Available in Base	SNOMED- CT Table it available and can be used to Assign a Diagnosis, Symptom or Test. It can also be used as a look-up. It can also be used in API or HL7 messaging to send information. Such use cases are built on custom requirements.
		Test, Measurement and Observation Codes: Regenstrief Institute - Logical Observation Identifiers Names and Codes (LOINC) Implementation Guideline: LOINC coding is to be	Available in Base	LOINC codes are available as a look-up table in the system on request. Same can also be provided as: a. Diagnosis option in tests / b. Communicate the

		used for processing results and reports with Laboratory and Imaging Information Systems. N.B.: SNOMED CT to LOINC coding interchange map is available from IHTSDO and Regenstrief Institute.		Test recommended / c. Communicate a Test or Investigation Result
		Classification Codes: WHO Family of International Classifications (WHO-FIC) 3.1 WHO ICD-10: International Classification of Diseases (ICD) and its derivative classifications 3.2 WHO ICF: International Classification of Functioning, Disability and Health (ICF) 3.3 International Classification of Health Interventions (ICHI) 3.4 International Classification of Diseases for Oncology (ICD-O) Implementation Guideline: WHO FIC codes are primarily used for aggregated information and statistical/epidemiological analysis for public health purposes derived from health records that contain patient care related information as well as information that is crucial for management, health financing and general health system administration. While SNOMED CT is to be used by health record systems for terminology, generated classification-based reports may require the use of WHO FIC codes. Classification based reporting, for statistical or regulatory purposes, may continue to use WHO FIC codes as mandated by the health regulatory, intelligence, and various research bodies. N.B.: SNOMED CT to ICD-10 coding interchange map is available from IHTSDO and WHO.	Available in Base	ICD-10 is available in the System to provide a final Diagnosis in the EHR
31	DATA STANDARDS FOR IMAGE, MULTIMEDIA, WAVEFORM, DOCUMENT	A health record system stores data records and files of various types in support of clinical functions. These data elements serve the purpose of documentary records of various diagnostic and prescriptive data or information generated. Therefore, a health record system must conform to the following standards for such data:		
		1 NEMA Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015	Optional	We ideally interface with a PACs solution. We internally recommend STRADUS which conforms to the given requirement
		Implementation Guideline: NEMA DICOM PS3.0-2015 is a comprehensive standard for handling and managing image (series or single), waveforms (such as those in ECG/EEG), audio (such as those in digital- stethoscope) and video (such as those in endoscope, ultrasound, etc.) data in medicine. A health record implementation is required to implement relevant DICOM Information Object Definitions (IODs) for supported data types in Part-10 compliant files. Where required and relevant, other features of standard such as services, display, print, and workflow may be implemented.	Optional	We provide a 3rd party DICOM viewer, which conforms to the requirement. We can introduce the required validations for storage if needed in our solution.
		2 Scanned or Captured Records:		
		2.1 Image: JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi	Optional	
		2.2 Audio/Video: ISO/IEC 14496 - Coding of Audio-Visual Objects	Optional	

		2.3 Scanned Documents: ISO 19005-2 Document Management - Electronic Document File Format for Long-Term Preservation - Part 2: Use of ISO 32000-1 (PDF/A-2) (ref: Best Practices and Guidelines for Production of Preservable e-Records Ver1.0 from MeitY, Govt. of India)	Optional	
		Implementation Guideline: The above mentioned standards are to be used for documentary data (scan for prescription, summaries, etc.) and data captured through traditionally non-DICOM compliant sources like picto-micrographs, pathological photographs, photographs of intramural and extramural lesions, etc. All data formats that can be converted into relevant DICOM format should be, as relevant, converted and communicated as secondary captured DICOM format. It may be noted that while no maximum image resolution has been prescribed, a sufficiently acceptable limit may be used to avoid unnecessarily large file that do not aid in correspondingly better interpretation or analysis.	Optional	Based on Client Requirement
32	DATA EXCHANGE STANDARDS	A health record system has to operate in a larger ecosystem of other components with which it must share or communicate data in order to capture and provide as comprehensible medical information as is practical. A health record system must therefore conform to the following standards:		
		1 Event/Message Exchange: ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	Optional	We support HL7 interfacing as and when required by the client
		2 Summary Records Exchange: ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)	Optional	
		3 EHR Archetypes: ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification [Also, refer to openEHR Service Model specification	Optional	
		4 Imaging/Waveform Exchange: NEMA DICOM PS3.0-2015 (using DIMSE services& Part-10 media/files)	Optional	
		Implementation Guideline: Implementation of exchange standards is expected to be at least for the scope of data captured or retained by the health record system. To explain further, full implementation of ANSI/HL7 V2.8.2 for each event and message is not required in health record systems but minimum implementation supporting the types of events and messages relevant to the system is required. Similarly, implementation/support of DICOM DIMSE C-Store and/or C-FIND/C-GET service is expected for IODs supported by health record system whereas implementation of WADO could be optional.	Optional	
33	DISCHARGE/TREATMENT SUMMARY FORMAT	Implementers must ensure that the logical information model includes data elements to satisfy requirements of the format for Medical Records as specified by Appendix-3 of Medical Council of India (MCI) Code of Ethics Regulation 2002 (amended up to Feb-2016). The printed reports should meet MCI	Available in Base	Report Format APPENDIX-3 FORMAT FOR MEDICAL RECORD (see regulation 3.1) Name of the patient : Age : Sex :

		prescribed formats whenever any discharge or treatment summary is prepared.		Address : Occupation : Date of 1st visit : Clinical note (summary) of the case: Prov. : Diagnosis : Investigations advised with reports: Diagnosis after investigation: Advice : Follow up Date: Observations: Signature in full ..... Name of Treating Physician
34	E-PRESCRIPTION	Pharmacy Council of India (PCI) has, in its recent regulation (Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI), provided the definition of the term under Section 2(j) that the term 'Prescription' includes the term 'electronic direction'. Implementers must therefore ensure that the logical	Available in base	Dispense against prescription required according to document and is available
35	HARDWARE	The IT hardware used should meet (and preferably be better than) the optimal requirements specified by the software (to be) used.	Optional	Dependent on the client
		The medical and IT hardware used must meet the relevant applicable specifications from BIS, NEMA, IEEE, ISO, CE, RoHS, EnergyStar, apart from Medical and IT standards for the equipment. A backup or data preservation mechanism should be put in place. Data capacity should be planned to meet the storage requirement as per the mandated rules / laws.	Optional	Dependent on the client
		System redundancy at various levels (disk, power, network, etc.) should be planned to meet the organizational system availability requirement.	Available in Base	On Server Side. AmazonAWS is HIPAA Compliant
		Network and data security should be planned, implemented, and periodically audited. Please see section on Security and Privacy for the various requirements and functions that need to be supported and implemented. Integrity: Audit log: Access Privileges: Access control: Automatic log-off: Authentication: Digital Certificates: Encryption:	Available	Level of Digital Certificates and Encryption is optional.
		Hardware should be checked periodically for correctness and completeness of operation expected from them. An appropriate maintenance cycle should be planned and rigorously followed.	Available in Base	Done on the Server Side.
		Planned and expected Capacity and Quality requirement of the organization should be met by the hardware used. Periodic updates and upgrades should be carried out to meet these requirements.	Available in Base	
36	NETWORKING AND CONNECTIVITY	Should be able to harness any telecommunications-related connectivity like the Internet, LAN, WAN, WAP, CDMA, GSM or even Cloud Computing that will permit the various EMRs	Available in Base	

		of an individual to be integrated into a single lifelong electronic health record		
		As far as is practical and affordable, the connectivity medium chosen should be reliable and fast enough to sustain a secure data exchange for the period expected for transaction of records and data.	Available in Base	Dependent on the client
		The speed of the connectivity medium should be chosen from among available options so as to provide an acceptable user experience and not cause software/system fault due to delays/noise/failure. Should be able to ensure that data exchange is performed in a secure manner to ensure data validity and non-repudiability	Available in Base	Dependent on the client
37	DATA OWNERSHIP	The physical or electronic records, which are generated by the healthcare provider, are held in trust by them on behalf of the patient	Available in Base	No data of one patient is displayed to another patient
		The contained data in record which are the protected health information of the patient is owned by the patient himself / herself.	Available in Base	In PHR data pertaining to that patient is only displayed. o patient can view another patient data.
		The medium of storage or transmission of such electronic medical record will be owned by the healthcare provider.	Available in Base	We manage the EMR on cloud according to client requirement. If installed on Clients Local Server, then the client owns the EMR responsibility
		The “sensitive personal information (SPI) and personal information (PI)” of the patient is owned by the patient herself. Refer to IT Act 2000 for the definition of SPI and PI.	Available in Base	The act states above points 37.1, 37.2, 37.3 should be fulfilled.
38	DATA ACCESS AND CONFIDENTIALITY	Regulations are to be enforced to ensure confidentiality of the recorded patient/medical data and the patient should have a control over this.	Partial	Client having control of the data can share to mis-use login or via e-mail.
		Patients will have the sufficient privileges to inspect and view their medical records without any time limit. Patient’s privileges to amend data shall be limited to correction of errors in the recorded patient/medical details.	Available in Base	The Patient can view all the finalized records from PHR and update limited fields in his/her profile.
		This shall need to be performed through a recorded request made to the healthcare provider within a period of 30 days from the date of discharge in all inpatient care settings or 30 days from the date of clinical encounter in outpatient care settings. An audit of all such changes shall be strictly maintained. Both the request and audit trail records shall be maintained within the system.	Available in Base	In Medixcel user can filter according to dates and the audit trail is available to him/ her. We do not delete any audit trail records.
		Patients will have the privileges to restrict access to and disclosure of individually identifiable health information and need to provide explicit consent, which will be audited, to allow access and/or disclosures.	Optional	Condition based access to internal users and external actors can be enabled based on workflow. Same has been designed for other clients.
39	DISCLOSURE OF PROTECTED / SENSITIVE INFORMATION	For use in treatment, payments and other healthcare operations: In all such cases, a general consent must be taken from the patient or next of kin, etc. as defined by the MCI.	Available in Base	Consent form creation / Digital Sign or Scan & attach option available.
		Fair use for non-routine and most non-health care purposes: A specific consent must be taken from the patient; format as defined by MCI.	Available in Base	Consent form creation / Digital Sign or Scan & attach option available.
		For certain specified national priority activities, including notifiable/communicable diseases, the	Optional	Data communication to feed national health portal can be added if needed

		health information may be disclosed to appropriate authority as mandated by law without the patient's prior authorization		
		Instances where use and disclosure without individual authorization will be possible are as follows: Complete record with all identifiers in an "as-is" state, on production of court order Totally anonymized data, where the anonymization process involves the complete removal of all information that allows the identification of the patient.	Available in Base	Configurations can be setup on request, such that 3rd party Doctors can access reports and provide notes without accessing patient demographic details.
40	RESPONSIBILITIES OF A HEALTHCARE PROVIDER	Protect and secure the stored health information, as per the guidelines specified in this document While providing patient information, remove patient identifying information (as provided in the list below), if it is not necessary to be provided	Available in Base	We don't share the Medical data with any third party
		Will ensure that there are appropriate means of informing the patient of policies relating to her/his rights to health record privacy	Available in Base	While login in to PHR. TnC are displayed to user. Even while enrollment the organization can set and welcome email with TnC
		Document all its privacy policies and ensure that they are implemented and followed. This will include: Develop internal privacy policies	Available in Base	The client shares their internal policy with us in terms of user types and their access to features, any TAT for Test etc
		Ensure implementation of privacy policies, audit and quality assurance Provide privacy training to all its staff	Available in Base	All features and policy of the application is communicated to the users while training
41	ELECTRONIC MEDICAL RECORDS PRESERVATION	Preservation of medical records assume significant importance in view of the fact that an electronic health record of a person is an aggregation of all electronic medical records of the person from the very first entry to the most recent one. Hence, all records must compulsorily be preserved and not destroyed during the life-time of the person.	Available in Base	MediXcel Application does not delete any data, it changes status to inactive
		Upon the demise of the patient where there are no court cases pending, the records can be removed from active status and turned to inactive status. HSPs are free to decide when to make a record inactive, however, it is preferable to follow the "three (3) year rule" where all records of a deceased are made inactive three (3) years after death.	Available in Base	Freezing Patient Data / Marking patient as Dead is Available
		It is however preferred, and the HSPs are strongly encouraged to ensure, that the records are never be destroyed or removed permanently. The health of the blood relatives and natural descendants of the person can be strongly influenced by the health of the person and on-demand access to these may prove to be hugely useful in the maintenance of the health of the relations.	Available in Base	No patient data record can be deleted once services are finalized
		Furthermore, analysis of health data of all persons is expected to greatly benefit in the understanding of health, disease processes and the amelioration thereof.	Available in Base	ICD 10 Coding available
		With rapid decline in costs of data archiving coupled with the ability to store increasing amounts of data that may be readily accessible, continued maintenance of such data is not expected to lead to any major impact on the overall system maintenance and use.	Available in Base	We have archived client data in the past

NABL / NABH Compliance

Our software is NABL / NABH compliant and is run by NABL compliant Labs and NABH compliant hospitals.

All norms mentioned specifically for MIS and Software are followed by mediXcel. All reports related to NABL / NABH can be generated from MediXcel or provided on request depending on the nature of the report.

Disaster Recovery Checklist

Plus91 and MediXcel have a Disaster recovery plan in place as per the IT and Security Policy. The below checklist is followed for all clients. A standard plan is in place for all customers hosted on our optimized, secured and tested AWS server configurations. For deployments on customer managed servers the same basic plan may be followed with some custom steps and configurations based on mutually agreed terms.

Below is a standard checklist of items we follow in our Disaster Recovery Plan

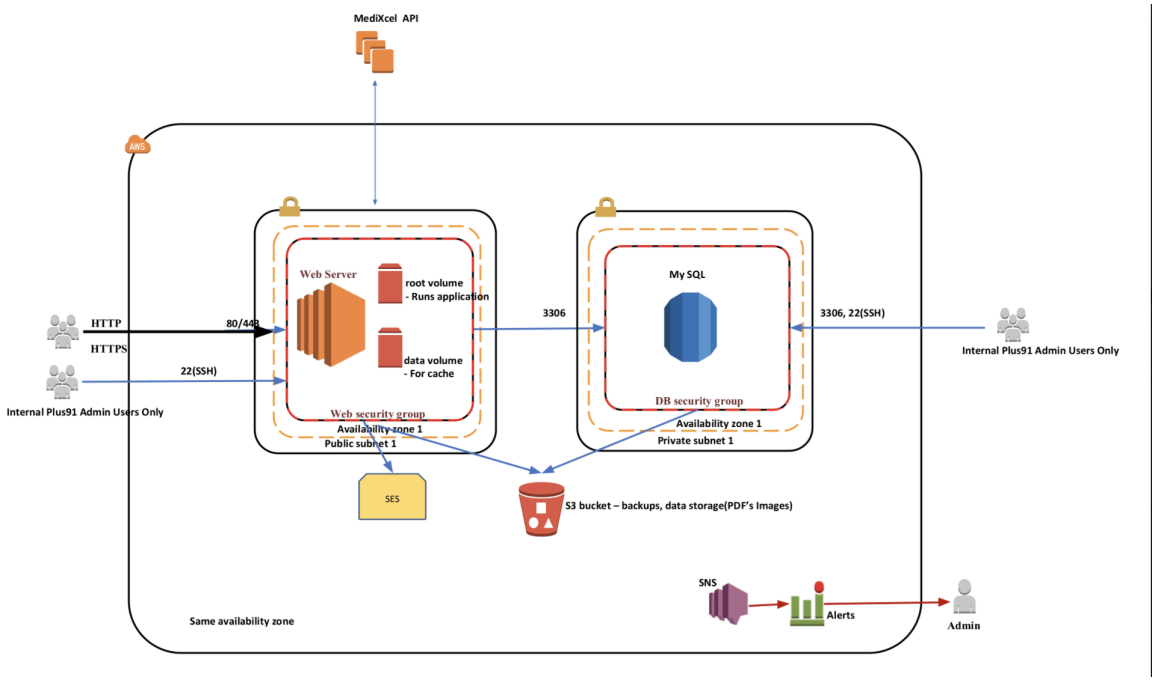
Sr. No	Check List Item	MediXcel Workflow	Notes
1	Indentify Data Storage Requirements	Based on modules planning to be used and current patient footfall and future plans estimate growth of database and file folder size	
2	Infrastructure Documentation	Confirm Infrastructure being used. Document infrastructure being used. Update document as and when infrastructure is augmented or changed for both Back-up / DR / Fail-safe.	
3	Setup Communication Channels	Sensitize client to DR process. Ensure communication protocol is explained, documented and shared. Correct people are referenced in the communication channel and the same is updated regularly.	
5	Setup Back-up process (as per client terms)	Back-up process is setup based on plan selected by customer with any custom riders.	
6	Setup DR workflow	DR workflow is setup for the customer	
7	Determine Recovery Time	Basic Recovery time test is done and logged.	

8	Test DR workflow	Test DR workflow for customers at mutually decided intervals	
9	Confirm Infrastructure (HW / SW / Security) is up to date	Confirm all related hardware and software is up to date and secure.	
10	Final Failback Mechanism options	Decide with customer and setup an external data back-up service if required	

Amazon AWS approved SAAS solution

Plus91 and MediXcel are an Amazon AWS approved healthcare technology vendor and a preferred ISV of AWS.

Below is our core architecture in deploying MediXcel on AWS in highly secure environments provided and approved by AWS to be compliant with all known healthcare norms.



Product - Project Delivery FAQs

The following section is relevant where significant customization and updates which are being done in the MediXcel code base for a client and there is an enhanced delivery cycle requiring documentation and project management.

a. SRS and Project Planning Documentation:
    1. Plus91 will hold a Joint Application Development workshop with the Client where the Client will provide the requirements.
    2. Plus91 will create and submit a System Requirement Specification Document (SRS) to the Client for Approval
    3. On signed approval Plus91 will submit a Project Plan for implementation and start execution as per the plan.
b. Development:
    1. Plus91 follows a dual Development Methodology depending on the below scenarios.
    2. Product Upgrades: For Product Updates and Upgrades Plus91 follows the Waterfall model, releasing upgrades every 6 months
    3. Client Customizations: For Client Customizations Plus91 follows the Agile Method of development. Team will provide rapid updates on the feature request and release to the testing team till the complete requirement is developed and tested as per the documented test cases. The Client will be shown regular updates and approval will be sought at regular intervals.
c. Review:
    1. Plus91 will conduct periodic project progress reviews internally to ensure compliance of process, quality and schedule
    2. The Client will assign a review team to review project development progress.
    3. Plus91 will share the project update on customizations (if any) online on a 3 to 5 -day basis
    4. On completion of the first version of a specific customization feature an online demo review will be done for feedback with the review team.
    5. The same will be communicated via e-mail 48 hours in advance to find a mutually available time for both parties.
        a. All reviews by the Client have to be done within 96 hours else it will be considered as approved.
        b. Subsequent reviews of the feature will be done post development update on the feedback is completed or/and on passing critical testing milestones.
    6. Plus91 will provide the project progress update based on the frequency decided in the Project Plan

d. Testing:

Plus91 will complete the following forms of testing on the base product delivered on the UAT server mentioned in Point b6:

1. Unit Testing
2. Functional testing

3. Regression Testing
4. Stress Levels of Testing.

e. Go Live:

1. Plus91, on sign-off by the client will setup the environment on the Live server
2. Plus91 will deliver the Base Setup package on the live server without any data except a Super Admin user to update configurations.
3. Plus91 will import live User, Test configuration and other Master data
4. Plus91 will perform a cleanliness check of the system and provide access to the Client to sign-off

f. Post Go-live:

1. Plus91 will provide all passed CRs for sign-off to the Client on the test server.
2. On sign-off by the Client, the updated code will be pushed to the Live Server using Atlassian Bitbucket.
3. The update to the live Server will be communicated in writing to the Client and down-time if any will be mutually discussed and agreed with the Client.
4. On confirmation from the Client, the code will be pushed to the Live server and a status update e-mail will be shared with the Client.
5. Tools Used: Note – tools are subject to change without prior notice
    1. Internal:
        i. Atlassian Jira / Trello – Project and Task Management
        ii. Google Meet – Team Communication
        iii. Atlassian Jira - Bug Management
        iv. Atlassian Bitbucket – Source code management
    2. External:
        i. Google Sheets / Atlassian Jira – Development Status
    3. Change Management
        i. Change Management can arise post signing-off the SRS or post Go-Live
        ii. Process Flow to be followed:
    4. For all changes that have been requested by the client via proper channels Plus91 will carry out a complete impact assessment and provide an impact assessment document, effort and timeline to carry out the change.
    5. The Client will review the impact assessment documents, effort and timelines and will provide Plus91 a written confirmation to carry out the change request for approved changes.
    6. All communication would be shared via an official e-mail.
        i. Customizations and future Change requests (CR):
            1. All customizations and CRs will be logged into the Google tracking sheets.
            2. Testing will be carried out on delivery of a complete feature or module or close ended update to the UAT server

3. All bugs detected on Customizations and CRs will be logged in Mantis.
4. Feature or Module will be provided to the Client to verify once 85% of the bugs have passed testing and no medium or high level critical bugs are pending.
5. On a case by case basis Plus91 will do Stress Testing or Regression testing based on the impact of the module on rest of the source code and database

h. Acceptance Criteria

Plus91 shall deliver the Licensed Software along with the agreed customizations discussed during the requirement gathering workshop and provide documentation to the client upon completion of testing at their end. The deliverables will be accepted based on the successful completion of Acceptance Testing conducted in accordance with client's Acceptance Criteria mentioned below:

1. The Client will initiate Acceptance testing within 1 week from the receipt of the deliverable. If during the testing period, client discovers an error in the Software or a substantial non-conformance to client's requirements, client will notify Plus91 in writing accompanied by documentation ("Error Reports") evidencing such error or non-conformance.
2. Plus91 shall provide client, a written mutually agreed remediation plan of the respective Error Report.
3. Plus91 shall provide client remedial Software; whereupon client will initiate resumption of Acceptance Testing.

Support and Maintenance FAQs

1. Note: All terms are subject to change without prior notification and are governed by the final terms provided in the agreement.
2. Bugs and Errors in the Software which fail to deliver the desired outcome
3. Personalization Updates during setup
    a. Staff Information
    b. Medical Template Edit
    c. Rate List Update
    d. Bulk updates on any other master in the database where data is provided in given format in Excel
4. Online Non-Technical Support from time to time
5. Time to time free product updates as decided by Plus91 for all its clients
    a. Confirmation from the client of the list of the upgrades with downtime
    b. If downtime is applicable confirmation of date, time and time for which downtime will be present
6. Maintenance of Server to ensure MediXcel is working as desired
    a. Weekly back up of data to be done via script
    b. Monitoring of SQL and Server Usage to flag and correct any Usage threshold crosses
7. Support Process:
    a. Process:
        i. Tool: A Uservoice setup will be included within the setup.
        ii. We will also be creating issue tracking google document mutually shared between teams to get a clear status on all defects and software issues.
        iii. Contact options:
            1. Via Altassian Jira Service Desk
            2. Provided Support E-mail Id
            3. Last Resort: Phone or Mobile Number provided
    b. Bug Severity levels:
        i. High: Prevents a major outcome from being completed and will be looked at in priority
        ii. Medium: Prevents a minor outcome from being completed and will be looked at in priority with respect to High level bugs from all clients
        iii. Low: Does not affect an outcome, will be looked during a monthly review and fixed
    c. SLA for Bug Resolution (TAT):

	High	Medium	Low
Confirmation of Receipt	Within 30 minutes	Within 30 minutes	Within 30 minutes
Resumption Time	2 Hours	4 Hours	24 Hours

Resolution Time	6 Hours unless specified as deep bug with a deadline to fix. In this case work around to be provided	8 Hours unless specified as deep bug with a deadline to fix. In this case work around to be provided	Up to 48 Hours or part of the Monthly Update depending on the impact of business

8. Plus91 will be hosting the Plus91 EMR and LIMS Software on Amazon AWS EC2 Cloud. Refer to the link: https://aws.amazon.com/ec2/sla/ for the SLAs and uptime
9. Sizing of the EC2 instances will be provided as part of the Hosting documentation within 30 days of the SRS being approved.
10. Escalation Matrix with contact information will be provided at the time Go-Live.
11. Warranty Period is for a period of 3 months from delivery of first version of the product on the live server.
12. Full-time semi-technical support can be hired from Plus91 at an additional rate of Rs. 125000 + Service Tax per month. The invoicing in such a scenario will be on a quarterly basis.
13. Support Hours:
    a. Standard Support Hours: Monday to Saturday: 8am to 8pm
    b. Plus91 will provide remote support and phone based support in case of Emergencies (E.g. Bug Severity – High / System is down) during non-standard support hours, Sundays and the 12 standard holidays as defined by the Plus91 calendar.

END of Document