

Pediatric Suite Implementation Guide

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Pediatric Suite Overview

Clinical Summary

Pediatric Suite is a provider-facing, patient-centered resource that brings pediatric clinical knowledge into the EHR workflow to improve health outcomes for infants, children, and adolescents.

Pediatric Suite includes the following modules:

Module	Abbr.	Short Description
Pediatric Growth Charts	GC	Display the growth measurements (height, weight, BMI, head circumference, weight to height) of a patient over a growth chart. Calculate the percentile of each measurement based on age and sex.
Blood Pressure Centiles	BPC	Display the blood pressure measurements of a patient and calculate the percentile based on age and sex.

Clinical Workflow Integration Summary

Pediatric Suite is embedded in the clinical workflow for vendor systems supporting the SMART on FHIR embedded launch flow. Using the SMART on FHIR embedded launch flow, Pediatric Suite will be available from the patient's chart as a link or button.

Patient Security and HIPAA Summary

Pediatric Suite has been designed and developed with protecting patient data as the primary concern. Pediatric Suite utilizes the SMART on FHIR specification to receive authorization from the EHR to the patient's data. Patient data is protected when in-flight using TLS 1.1/1.2. Pediatric Suite does not store PHI at rest. Interopion provides Pediatric Suite in a HITRUST 9.1 offering.

See the Appendix for EHR vendor-specific validation/security details.

Installation Support Summary

Pediatric Suite is installed using this guide and the EHR-specific instructions for SMART on FHIR apps. Interopion will provide assistance during the installation process.

See EHR Integration for details.

Customer Support Summary

Primary customer support is usually handled by a healthcare site's help desk (to provide a consistent model across apps). Interopion will provide escalated support to the site's help desk as well as technical support for Pediatric Suite.

Document References

The following documents are referenced as part of this guide:

Document	Details
<i>Interopion Privacy Policy</i>	Policy concerning client information gathered by Interopion, Inc., including gathering, use, disclosure, and management of data.
<i>interopiO App Engine Support Model</i>	Pediatric Suite support models including: <ul style="list-style-type: none"> - Installation Support - Customer Support - App Technical Support - App Software Support including impact assessment, incident notification, resolution, resolution notification, and retrospective.
<i>Pediatric Suite Terms of Use</i>	Policies that must be agreed to by the client to use Pediatric Suite.
<i>interopiO Terms of Use</i>	Policies that must be agreed to by the client to implicitly or explicitly use interopiO.
<i>Pediatric Suite BAA</i>	Business Associate Agreement between the healthcare site as Covered Entity and Interopion as Business Associate. This agreement is created for each client healthcare organization (often from a template provided by Interopion).
<i>Pediatric Suite App Licensing Agreement</i>	Agreement, or sales contract, between the healthcare site and Interopion to make the Pediatric Suite available for use by site clinicians for site patients. This agreement is created for each client healthcare organization (often from a template provided by Interopion).

EHR Integration

System Requirements

Requirement	Details
EHR support for SMART on FHIR Embedded Launch	Pediatric Suite supports the practitioner-launched, patient-context flow.
HL7 FHIR DSTU2	Pediatric Suite will issue HL7 FHIR DSTU2 queries for the patient. See Query Details.
Internet Explorer 11 or greater, or Chrome	Pediatric Suite requires a web browser or web component that has compatibility with IE 11 or greater, or Chrome.

Pediatric Suite Registration

The following values are representative for an installation of Pediatric Suite. Actual values will be provided by Interopion at the time a healthcare site configures Pediatric Suite within their EHR instance.

Registration Element	Value
Scopes	launch launch/patient patient/Encounter.read patient/Observation.read patient/Patient.read patient/FamilyMemberHistory.read openid profile online_access
Launch URL	https://ps.interopion.com/hub/launch.html
Redirect URL	https://ps.interopion.com/hub/

SMART Scopes

Scope	Purpose
patient/Patient.read	Reading the patient resource is required by the suite to display demographics data. Growth chart and Blood Pressure centiles also require to be aware of the patient's age, which is calculated in real time, based on the patient's birthdate.
patient/FamilyMemberHistory.read	Growth Chart requires to read a patient's family member history to be used in the parental view for the displaying the parent's heights and calculate the patient's expected mid-parental height.
patient/Observation.read	Reading the patient's observations is required by Growth chart to display the height, weight, head circumference, BMI, bone age measurements to be displayed in the Growth Chart graphs and tables. Growth chart also loads the patient's gestational age that can be used to display gestational correction on the graphs. Blood Pressure Centiles requires to read height, Systolic BP and Diastolic BP to calculate and display the blood pressure values and percentiles.

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patient/Encounter.read	Blood Pressure Centiles requires to read specific encounters linked with systolic and diastolic blood pressure measurements to display additional information for each measurement and to allow additional filtering options.
launch/patient	Allow launching outside the EHR and ask for a patient to be selected at launch time.
launch	Allow to obtain launch context when app is launched from an EHR.
online_access	Allow a refresh_token to be obtained on launch that can be used to obtain a new access token to replace an expired one as long as the end-user remains online.
openid and profile (fhirUser)	Allow the app to retrieve information about the current logged-in user.

SMART Launch Context Standard Elements

Context Element	Supports?	Notes
"patient"	Yes, Required	Patient.id
"encounter"	No	n/a
"need_patient_banner"	Yes, Optional	Will show patient banner if "need_patient_banner" is "true"
"intent"	Yes, Optional	See 'Intent Configuration' section for details
"smart_style_url"	No	Not supported

SMART "Intent" Configuration

Intent parameters are supported in the following format:

intent=nameShort:{MODULE ABBREVIATION}|primary:{PRIMARY GROWTH CHART}|secondary:{SECONDARY GROWTH CHART}

Examples:

intent=nameShort:GC|primary:CDC|secondary:WHO
intent=nameShort:BPC

The parameters **primary** and **secondary** are applicable only to the Growth Charts module.

Intent Key	Intent Values	Key in example
nameShort	GC BPC	MODULE ABBREVIATION
primary	CDC WHO	PRIMARY GROWTH CHART

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	DS OLSEN FENTON	
secondary	CDC WHO DS OLSEN FENTON	SECONDARY GROWTH CHART

Pediatric Suite Support

See *interopiO App Engine Support Model* for details.

Implementation Support

As part of each EHR vendor validation process for Pediatric Suite, the EHR vendor will prepare a set of instructions for configuring the app within the healthcare site EHR instance. The EHR vendor will also assist in configuring the app according to their program details.

Interopion will assist a healthcare site configure Pediatric Suite by providing this guide, a help center portal and ticketing system, and a support email channel. In addition, Interopion will attend online meetings as needed to assist the site healthcare team (along with the EHR vendor assistance) to successfully configure Pediatric Suite.

Some healthcare sites have additional and lengthy validation, staging, and promotion processes. Interopion will participate in these processes as desired at Interopion’s standard support billing rate.

Customer Support

Pediatric Suite will endeavor to integrate within the healthcare site’s existing support model as follows:

Support Group	Provided By	Details
Front-line Support	Healthcare Site Internal Support	Clinicians will contact their existing healthcare site’s help desk for issues with Pediatric Suite. It is expected that the healthcare site will develop their own knowledge base over time for Pediatric Suite, reaching out to Pediatric Suite’s Customer Support as needed.
Pediatric Suite Customer Support	Interopion’s Help Desk	A healthcare site’s help desk will reach out to Interopion’s Help Desk for issues concerning Pediatric Suite. Interopion’s Help Desk will provide self-help (FAQ, guides, knowledge base), ticketing, and email support.
Pediatric Suite Technical Support	Interopion’s Pediatric Suite Support Team	Unresolved issues reported by the healthcare site (as well as all other support issues) will be escalated to the Pediatric Suite support team. This team will address runtime issues (availability, configuration, trouble-shooting, security issues) and software issues (bugs, feature requests). This team will also handle notification when appropriate or as required by law.

HL7 FHIR API Queries Issued

For each query identified, the Pediatric Suite will issue the FHIR API query one time per session, according to the module utilized. If the query is issued for one module, Pediatric Suite will make the query result available to any other module without querying the EHR. This is in an effort to conserve queries and their associated cost. If it is required to obtain a query value that has become available within the EHR after the app has been open, simply close the app and open it again for the patient.

Read

Subject	Module	Query
Patient Demographics	GC, BPC, BRC	Patient/{patient.id}

Search

Subject	Module	Query
Patient Growth Chart Measurements	GC	Observation?code=http://loinc.org 37362-1,http://loinc.org 18185-9,http://loinc.org 11884-4,http://loinc.org 39156-5,http://loinc.org 8287-5,http://loinc.org 29463-7,http://loinc.org 3141-9,http://loinc.org 8302-2&patient={patient.id}&_count=100
Patient Growth Chart Family Member History	GC	FamilyMemberHistory?relationship=http://hl7.org/fhir/v3/RoleCode FTH,http://hl7.org/fhir/v3/RoleCode MTH&patient={patient.id}&_count=100
Patient Blood Pressure Percentiles Measurements	BPC	Observation?code=http://loinc.org 55284-4,http://loinc.org 8302-2&patient={patient.id}&_count=100
Patient Blood Pressure Percentiles Encounters	BPC	Encounter?_id={encounter.id},{encounter.id},...&_count=100

Codes used in EHR Queries

Module	System	Code	Resource	Description
GC	http://loinc.org	37362-1	Observation	XR Bones bone age
GC	http://loinc.org	18185-9	Observation	Gestational age
GC	http://loinc.org	11884-4	Observation	Gestational age Estimated
GC	http://loinc.org	39156-5	Observation	Body mass index (BMI) [Ratio]
GC	http://loinc.org	8287-5	Observation	Head Occipital-frontal circumference by Tape measure

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GC	http://loinc.org	29463-7	Observation	Weight
GC	http://loinc.org	3141-9	Observation	Weight
GC, BPC	http://loinc.org	8302-2	Observation	Height
GC, BPC	http://loinc.org	55284-4	Observation	Blood pressure combined
GC	http://hl7.org/fhir/v3/RoleCode	FTH	FamilyMemberHistory	Father
GC	http://hl7.org/fhir/v3/RoleCode	MTH	FamilyMemberHistory	Mother

EHR Vendor Implementation Playbook

Healthcare Site Integration of the Interopion Pediatric Suite

Participants

Participant	Role	Contact Info
Healthcare Site Biz	Contracting	
Healthcare Site IT	Configuring the EHR Vendor EHR	
Healthcare Site Clinical	Using and testing the app	
Healthcare Site Support	Front-line support for the Pediatric Suite	
Interopion Account Team	Contracting	Marketing@Interopion.com
Interopion Installation Support	Assist Healthcare Site IT as needed	Support@Interopion.com
EHR Vendor Installation Support	Provide Vendor Implementation Guide, assist Healthcare Site IT as needed	EHR Vendor Technical Support for: 1) Healthcare Site's EHR Vendor Account Support 2) Interopion's EHR Vendor Account Support

Activities

Step	Description
EHR Vendor App Store	Pediatric Suite is available at from EHR Vendors' app store
Contracting	Contracting for the Pediatric Suite has been completed. These documents are active: <ul style="list-style-type: none"> - Pediatric Suite App Licensing Agreement - Pediatric Suite Terms of Use - Interopion Privacy Policy - Pediatric Suite BAA between the healthcare site and Interopion
EHR Vendor releases Pediatric Suite	At the request of Interopion, the EHR Vendor releases the Pediatric Suite (installation key) to the Site's EHR instance
Healthcare Site IT configures Pediatric Suite	Using this guide, Healthcare Site IT configure Pediatric Suite within their EHR instance for the appropriate launches and appropriate clinical users. <i>Note: this may be to several environments including Test, Stage, and Prod depending on the Site's processes. See EHR Integration section for details.</i>
Healthcare Site supports Pediatric Suite	Healthcare Site Support is aware of Pediatric Suite and prepared to handle front-line support. See Pediatric Suite's Support Policy.
Healthcare Site Clinical uses Pediatric Suite	Healthcare Site Clinical use the app. Refer to the Pediatric Suite User's Guide for details.
Installation is completion	The Healthcare Site accepts the implementation as complete.

Appendix

Appendix A: Epic App Orchard Validation Questionnaire Response

The following questions and answers refer to the runtime deployment of the Pediatric Suite app encompassing all application tiers and application service providers as a single view for the EHR.

Safety Requirements

Epic Question	Interopion Answer
Summarize (or provide a link to) your organization's process for identifying, triaging, and resolving critical issues, such as patient safety concerns or financial risks.	When an issue is reported, our first action is to assess the severity of the issue, and assign it a severity level. This severity level describes the nature of the issue and how impactful it would be to any user. It does not define the scope of impact (i.e., how many users are impacted). High severity issues are resolved as soon as possible. Patient Safety issues that are validated by our Clinical team are “drop everything” events. Issues with impact on patient care are prioritized above those that impact business operations. Issues that impact business operations are prioritized on the basis of how severe the impact is to a practice, and how long the functionality can remain “broken” without causing severe impact to practices
What timelines does your process for identifying, triaging, and resolving critical issues follow?	High severity issues are resolved as soon as possible. Patient Safety issues that are validated by our Clinical team are “drop everything” events
Summarize (or provide a link to) your organization's process for proactively communicating critical issues to customers.	We directly reach out to customers through email.
What timelines does your process for proactively communicating critical issues follow?	For problems or issues that severely impact a significant amount of users or any mission critical issue for a single user will be proactively communicated within 8 hours of being discovered.
What system(s) do you use to track bugs and customer-reported issues? (For example, JIRA, Zendesk, Trac, etc.)	We use Zendesk to track bugs and customer reported issues.
Does the app present data that could negatively impact safety if misinterpreted?	Yes
What standards does the app adhere to for accessibility and usability?	We are striving for WCAG 2.1 Level AA accessibility standards in Pediatric Suite
Does the app search for patient records?	No
Do users interact with the app's UI?	Yes
Is the app embedded in Epic with patient context?	Yes

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How does the app maintain patient identity across multiple sessions?	Each session must complete the SMART on FHIR launch flow individually. We rely on Epic to close our app if the patient in the EHR changes. We use the SMART launch state parameter to provide name-spacing of the concurrent session storage.
Does the app take reasonable steps to present all relevant data in a single view for users making decisions?	Yes The app queries relevant clinical data and displays them on screen for the user to make the appropriate decision.
Could the user reasonably encounter a workflow in which data might become stale, impacting the function of the app? (For example, a user might encounter out-of-date data during a loss of connection or timeout.)	No
Explain how the data cannot become stale.	The app is not intended to be used for a long-running transaction. The only way the data would be stale is if the app is opened and then a new resource is created for the patient. This is unlikely since the app workflow is short-lived.
If the app displays medications, does it utilize TALLman lettering in the display of medications?	N/A - The app does not display medications.
Does the app utilize selection lists?	Yes
If filters are applied, are they obvious, reversible, and repeatable?	Yes
If a selection list has values that could be confused, does the app help users distinguish between options by prominently displaying the most useful information? (For example, displaying medications in TALLman lettering.)	N/A - The selection list has values that cannot be confused. All selection lists in the app clearly indicate the purpose behind the control. The app does not list medications. When listing measurement units the options are clearly distinguishable and cannot be confused.
Does the app make calculations that are stored or displayed to users? (For example, converting weight from pounds to kilograms or calculating a score.)	Yes
Does the app display details on how the calculation was done?	Yes
Do users have sufficient guidance to properly interpret a calculated result? (For example, is it clear whether a high score is good or bad?)	Yes
Can users review and correct data entered into the app?	N/A - No data is entered into the app by users.
Could abbreviations used in the app be easily mistyped or misinterpreted? (For example, the "l" and "k" keys are next to each other on the keyboard; if the app permits "l" or "k" instead of "lb" or "kg" for weight entry, it is easier for a user to mistype the abbreviation.)	No
Can the app handle hidden or inappropriate control characters that may lead to unintended truncation or other display issues?	Yes
Will the app maintain backwards compatibility after each update to it such that historical data can still be referenced?	Yes.
When appropriate, does the app notify users of errors that may impact its proper or safe use?	Yes

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In scenarios when an error occurs but it is inappropriate to notify the user of that error, does the app notify administrators of the error?	Yes
Are users and administrators notified of errors in a timely manner and within the appropriate workflow?	Yes
Are errors displayed to users in a clearly understandable manner?	Yes
Are errors displayed to users in a consistent format to allow for easy recognition?	Yes
When possible, are actionable steps for addressing errors displayed to the user?	Yes
Are programmatic guardrails in place to ensure the app does not remain in a persistent problematic error state? (For example, inappropriately handling caught exceptions.)	Yes
Are partially completed workflows handled in a manner that minimizes user or system generated errors? (For example, interruptions resulting from abrupt termination of the app or connection issues.)	Yes

Security Requirements

Epic Question	Interopion Answer
What network architecture does the app use?	The app is cloud-hosted.
Which version(s) of TLS does the app support?	TLS 1.1 TLS 1.2
Does the app require any encountered TLS certificates to be valid, including checking revocation status?	Yes
Does the app launch from Epic?	Yes
Does the app use Epic's SMART on FHIR EHR launch to authenticate when launching from Epic?	Yes
How does the app verify that a user is authorized for use?	The app follows the SMART on FHIR model where the app is made available to users at a site as part of registering the app at the site. Only those users that are authorized to use the app will be able to see the app.
Does the app invoke any web services with Epic?	Yes
Does the app use an OAuth 2.0 access token to authenticate all web service calls to Epic?	Yes
Does the app share an Epic authentication token, such as an access or refresh token, with other systems?	No
Does the app store authentication tokens?	Yes
Explain how the token is protected.	The token is stored in an encrypted database and encrypted in transit using SSL.
If the app stores user credentials, financial account	No

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information, or other sensitive information, is this data always obfuscated when stored such that the app does not know the plain text information?	
Explain the hashing or encryption methods used.	The database is encrypted by the AWS RDS service using AES-256 encryption.
Has your organization developed your own cryptography libraries for use by the app?	No
Explain your process for taking updates, particularly to address security or privacy concerns.	<p>We use containerized deployments to isolate the application from the host machine. As we build the image, our vulnerability scans flag any security issues with the source code or libraries. We build using the official Ubuntu image. When deployed, we monitor and report on the compliance of the image daily. If security vulnerabilities are discovered, we assess the risk, create a new version of the app and deploy it through our normal CI/CD processes, ensuring a quality build and deployment. Deployments are scheduled to minimize downtime.</p> <p>We monitor and report on the container hosts for security compliance. We update the host virus definitions daily. Our reports include compliance of the virus scan definitions and the OS packages. If security issues are found, our processes automatically create tickets to address the issues. The issues are addressed according to their severity and priority. Container deployments are managed among container hosts to minimize downtime.</p>
Has your organization developed your own authentication libraries for use by the app?	Yes
How is your library kept up to date, particularly in response to a security or privacy concern?	We utilize NPM and Spring Security libraries to support the SMART authorization flow. We run vulnerability scans of the source code and libraries with each release of the software.
How is the app tested for security vulnerabilities?	The app source code is tested for vulnerabilities with each release version of the source code. The runtime system is scanned using a penetration testing service. The app is hosted in a HIPAA compliant, HITRUST 9.1 certified environment.

Privacy & Data Use Requirements

Epic Question	Interopion Answer
Does the app use interfaces to exchange data with Epic? (For example, HL7v2 or X12.)	No
Does the app use Kit?	No
If the app has workflows where patients would be presented with the Data Use Questionnaire, are the responses complete and up to date?	N/A - The app is not patient-facing.
Provide a link to your privacy policy. If one is not publically available, submit a copy of your privacy policy to your App Orchard TS.	
Does the app read data from a customer's Epic software?	Yes

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Explain the data retrieved and the methods used to retrieve it.	The app uses the FHIR API to read the patient's demographics, observations, family history, encounters.
Does the app write data to a customer's Epic software?	No
How and where do you use the data that the app obtains from a customer's Epic software?	The app shows the patient demographics and blood pressure observations to show a over-time chart and calculate Blood Pressure Centiles. The app also shows patient demographics, and weight/height/BMI observations in its growth chart module, and uses FamilyMemberHistory to calculate projected average child height based on parent history
Do you retain data processed by the app?	Yes
How long do you retain data processed by the app?	The application will retain data for as long as the customer uses the app.
What will happen to that data if your company merges, dissolves, or is acquired?	What would happen to any retained data processed by the app in the event of a merger, dissolution or acquisition involving Interopion cannot be stated with specificity at this time because the answer depends on the precise nature of the transaction at issue. However, Interopion would endeavor to ensure that any data-related issues that arise in connection with any merger, dissolution or acquisition are handled in compliance with the applicable business associate agreement with each of our affected customers, as well as applicable law and regulation
Is there any secondary usage of the data the app collects other than internal product improvement? (For example, transferring data to a third party or allowing any third party to access the data provided by you or the app.)	No
Summarize (or link to) your process(es) for notifying customers of potential and actual security breaches, losses (or theft) of data including protected health information, or other privacy issues.	We have contact information for all of our customer installations. For any potential or actual security breaches, losses or theft of data, we will contact the customer immediately and directly, and disclose the issue without a dependency on a solution to the issue being in place. We will work quickly and diligently to provide a solution to the issue.
What is your timeline for notifying customers of potential and actual security breach, loss (or theft) of data including protected health information, or other privacy issues?	We provide initial notification as soon as a breach or privacy issue has been identified. We classify all issues involving PHI as High Impact, and immediately work to remedy the issue. See our interopio App Engine Support Model for further details
Do you obtain consent from the app's customer or users to obtain, write, or retain data from its Epic software and for any secondary use or access to the data, including transfer to, or use by, a third party?	Yes
How do you obtain consent for the patient data that the app accesses?	Implied Consent
How is this covered in your agreement with the customer organization?	A customer provides consent at a healthcare organization level as part of the contracting process. Interopion obtains consent to use the patient data that the app accesses in the BAA with each customer.
Does the app obtain or write data to Epic via any methods not documented on the app submission?	No

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Does the app modify Epic-released code or include M code to be installed on the Epic database server?	No
Is any of the data obtained by the app from Epic sold to any third-party entity?	No
Is any of the data obtained by the app from Epic sold to any third-party entity?	No
Does the app offer proxy access to data for other apps or third parties?	No
How does the app ensure that user access to data obtained from a customer's Epic software is audited (including what data was accessed, when it was accessed, who accessed it, and for what purpose)?	We rely on Epic's auditing structure.
Is administrator access audited for data obtained from a customer's Epic software (including what data was accessed, when it was accessed, who accessed it, and for what purpose)?	Yes
Do you provide clear directions to customers or users of how they may stop the app from reading, writing, or retaining data?	Yes
Do you provide clear directions to customers or users of how they may delete or correct the data the app has already obtained from a customer's Epic software?	Yes

Reliability & Scalability Requirements

Epic Question	Interopion Answer
Does the app make scheduled API calls?	No
How many API calls, on average, does the app make per user or patient workflow?	Explain: The app makes 5 calls to the FHIR APIs on average.
Does the app provide programmatic guardrails or recommendations to minimize the impact on the customer's system? (For example, limiting the maximum number of concurrent API calls.)	No, we do not expect a large number of concurrent API calls
Are user workflows synchronous?	Yes
What is the average response time (in milliseconds)?	500 ms
In scenarios where users will wait for a response, what is the user experience?	The customer is shown a "loading..." message while the data loads.
In scenarios where users will wait for a response, what is the user experience?	The app is primarily a client-side web app. The app is deployed to an auto-scaling infrastructure that will grow as required to satisfy increased usage
Describe how you have tested the app with Epic.	We have run all aspects of the app using the App Orchard launch simulator and also tested the app with the assistance of our Epic account representative. We will also conduct pilot activities with the app and Epic healthcare sites
Describe any additional validation needed to perform with a customer prior to going live with the app in the system.	No additional installation actions are required at new customer locations

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As described in our Implementation Guide, the customer must use the Epic settings to create an Epic Type for the app, and provide mapping from Epic's protocols to Interopions regimens.	No
In what countries will the app be available for installation?	United States
Does your organization provide support to customers for the app?	Yes
Describe the support you provide for the app during the hours of operation during which it's likely to be used.	The support and hours of operation for the app are outlined in the BAA with each customer. Support hours are available from 10 am to 6 pm Eastern

Data & System Integrity Requirements

Epic Question	Interopion Answer
Does the app make scheduled API calls?	No
Does the app require or assume any third-party software, modules, or features to be installed in order to function?	No