March, 2020

# PROPOSAL

## COVID-19 Telehealth Patient Stratification Solution

Powered by **inCytes™**


PRESENTED BY:

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# RegenMed

March 26, 2020

The attached describes an EMR-grade telehealth solution to evidence-based and longitudinal COVID-19 patient stratification (among many other use cases). It is immediately deployable. Salient features include:

- ***Evidence-based pre-, peri- and post-clinical applicability.*** Quickly implement stratification protocols, whether existing or user-customized. Objective decision-support through simplified or sophisticated scoring systems at any stage of the patient pathway.

- ***Turnkey, Comprehensive, Scalable.*** An integrated and platform-agnostic solution easily deployable by one or more hospitals, departments and/or clinics with full cross-functionality.

- ***"Team" Care; "Circles" Data Sharing:*** Create Team of HCP's with shared PHI access and layered responsibilities for Case management. Create Circles of HCP's, administrators, researchers and others to collect, share and analyze verifiable, de-identified and aggregated clinical evidence in real time.

- ***Longitudinal and Integrated Real-World Evidence.*** Automatic creation of and 24/7 accessibility to protocol-specific, clinically-relevant registries. Robust report-building functions support statistically significant correlations for clinical and policy decisions, reimbursement support, patient and public communications.

- ***Public Engagement.*** A secure, continuous and engaging user experience for patients and concerned individuals.

- ***Other.*** Cloud-based; always on. Highly scalable. HIPAA/GDPR-compliant. Multi-lingual. Product-agnostic. Adaptable to clinical/scientific developments. Ongoing clinical, scientific and technical support. Integrates with existing websites, telehealth or other patient outreach initiatives. Export to existing EMR systems now or later. Low-cost.

Please contact me at ntierney@rgnmed.com for further information.

Sincerely yours,

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**GENERAL:** Full deployment in 10 – 14 business days. Key elements, including select platform screenshots and accompanying text, can be found in Appendix A. Definitions of ***bolded, italicized*** terms can be found in Appendix B.

## DEPLOYMENT SCHEDULE

***Day 1*:** Based on a survey form provided by Regen Med, Client provides the following information:

1. Desired ***Queries*** for the initial ***Observational Protocol.*** Ideally, include references to the ***Clinical/Scientific Sources of Truth*** for such Queries. Such sources may be based on existing CDC or other agency protocols, or may be established by the Client based on its own clinical/scientific experts.
2. ***Sponsor***, ***Users***, ***Circle Founder***, initial ***Circle Members***, ***Team Members.***
3. Roles/Permission sets for Circle Members and Team Members.
4. ***Scoring*** system (if any) and associated ***Outlier Alerts***.
5. Content for ***Patient Reports***. (May be supplied by Regen Med if desired.)
6. Schedules for automated patient notifications/communications.

***Day 7:*** Based on the foregoing information, Regen Med makes a preliminary version of the Client-specific platform available for on-line (real-world conditions) testing by all authorized Team and Circle Members.

***Day 10:*** Client provides desired corrections and adjustments to preliminary platform structure.

***Day 14:*** Regen Med provides final platform version to Client, available for immediate deployment.

**COST:** US$5/***Case*** | $35/month/***User*** | Contact us for other terms and services.

**APPENDIX A:** Key Elements

**APPENDIX B:** Definitions

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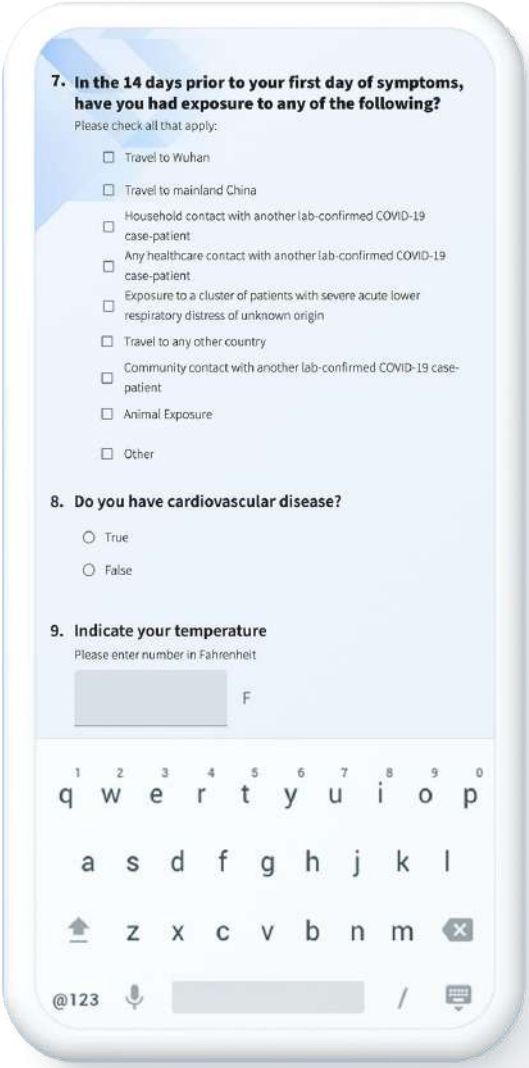
## APPENDIX A: KEY ELEMENTS

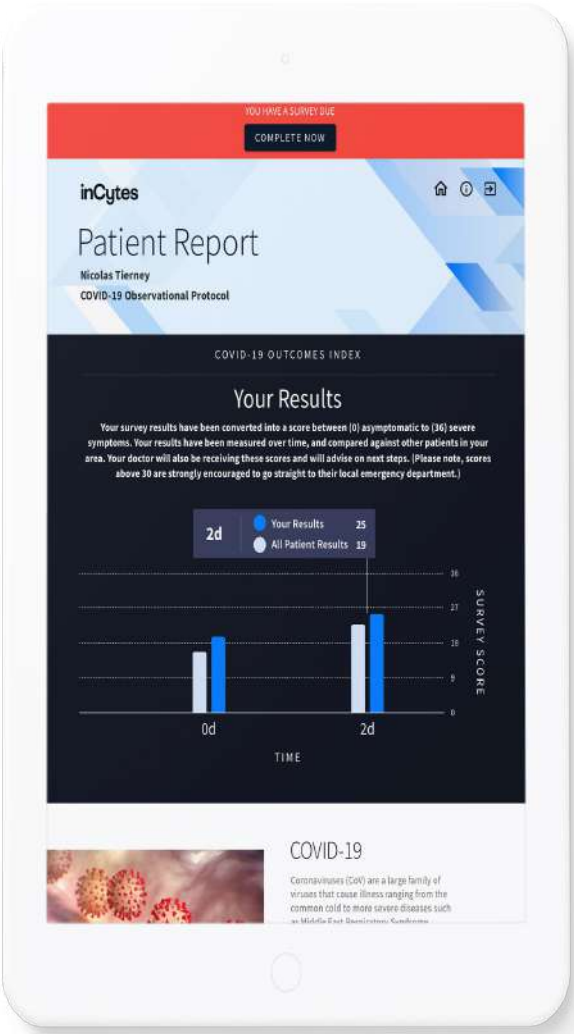



Instantly deploy an online telehealth solution to monitor, stratify and engage diagnosed and prospective COVID-19 patients.

**Features:**

1. Embed link in your native site/app
2. Patients self-enroll and e-sign consent
3. Patients complete configurable COVID-19 e-CRFs
4. Automated, email-based longitudinal follow up
5. Mobile, tablet, desktop accessible
6. HIPAA/GDPR Compliant

# 1. COVID-19 Electronic Case Report Forms (E-CRF)

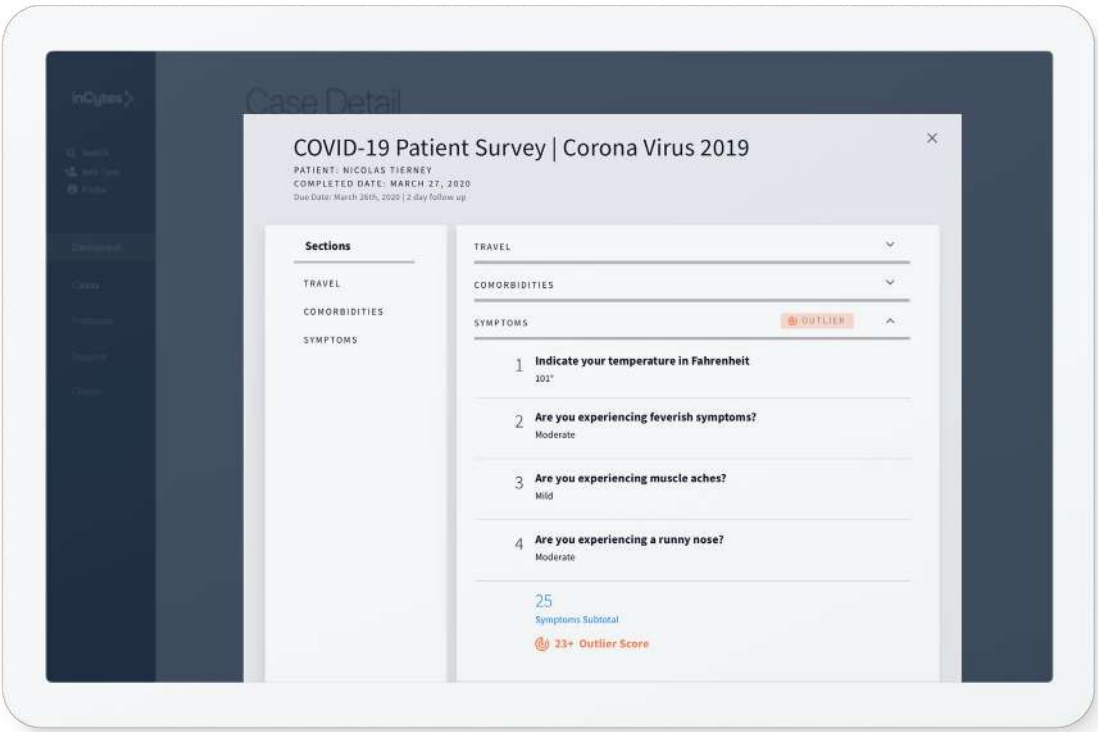



Provide immediate, substantive and automated feedback to motivate regular follow-up and ensure evidence-based admissions.

**Features:**

1. Patient responses convert into quantifiable scores
2. Scores are visualized through engaging graph
3. Patients benchmark against prior results and similar cohorts.
4. Custom educational modules
5. White-label branding

# 2. Personalized Patient Reporting




Clinical Teams receive alerts for high-risk subjects, allowing for immediate review and determination of appropriate action, including telehealth.

**Features:**

1. Score thresholds flexibly configured by Provider
2. Outliers trigger automated notifications to clinical team
3. Robust delegation enables clinically efficient team management
4. Patient results immediately accessible for telehealth contexts
5. Integrate with clinical e-CRFs, such as specimen submissions

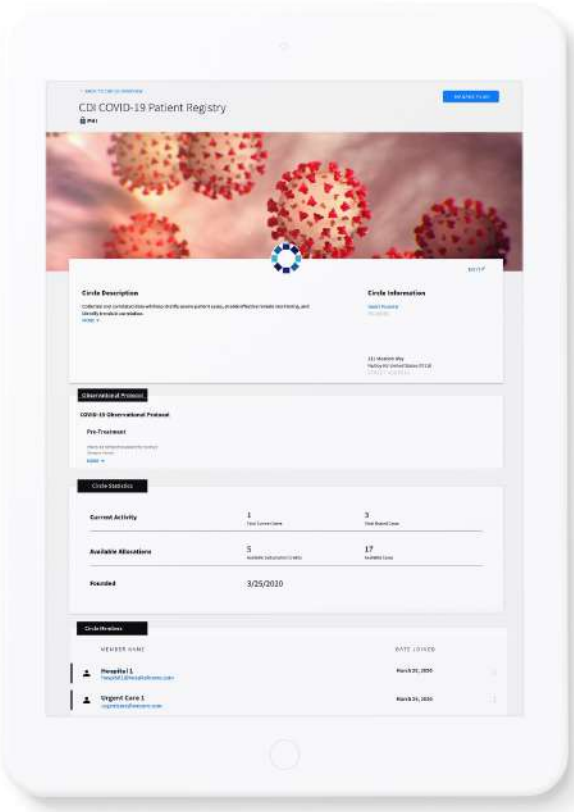
# 3. High Risk Alerts To Provider


Aggregated patient results available for cohort-based analysis, supporting improved patient stratification, evidence-based treatments, regional COVID-specific analysis, patient compliance and more.

**Features:**

1. Aggregated case data across multiple users, departments or sites.
2. Flexible X/Y axis and filter definitions for multi-variable analysis
3. Correlate custom observations to outcomes
4. Export to .CSV for further analysis

# 4. Aggregated, Integrated, Correlatable Patient Stratification




Large-scale, turn-key deployment across multiple sites, expediting aggregation and interpretation of statistically significant evidence.

**Features:**

1. Standardize results around shared observational protocol
2. Invite and enroll members through simple email, not installation
3. Manage membership, PHI permissions, subscriptions, and more through centralized dashboard.
4. Interpret shared results across through single, flexible report builder

# 5. Multi-Site Deployment and Collaboration

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## APPENDIX B: DEFINITIONS



| | |
|---|---|
| Case | The longitudinal pre-, peri- and/or post-clinical data and evidence collected against an Observational Protocol with respect to a single Patient. |
| Case Report Forms | The digital forms on which data is entered against Queries. Case Report Forms can be designed to filled out by a Patient (for example, patient reported outcomes measurements), or a Team Member. |
| Circle | A Circle is defined by (i) a specific Observational Protocol, (ii) a pre-defined group of one or more healthcare professionals, their assistants, hospital administrators, researchers or others, and (iii) the clinical evidence derived from Cases based on that OP. A Circle supports multi-center collection and analysis of clinical data and evidence, regardless of departmental, hospital or even national borders.<br><br>The Circle Founder invites Members to a Circle, and sets roles/permission sets for each such Member. One important such permission is access to PHI. |
| Circle Founder | The individual responsible for inviting Members to join the Circle, and setting the role/permission sets for those Members. A Circle Founder can be a representative of a Sponsor, a hospital department, a payer, a medical ethics committee or other individual or entity. |
| Circle Member | A healthcare professional, physician assistant, nurse, hospital administrator, researcher or other invited by a Circle Founder to join a Circle, and which has accepted such invitation. |
| Circle Registry | The real-world data aggregated by the Circle Members and Circle Founder against a shared Observational Protocol. |
| Circle Report | Any report generated by a Circle Founder, or any Member with permission to generate such reports, based on more Circle Registries. |
| Clinical/ Scientific Source of Truth | The clinical/scientific basis for a Query, typically determined or approved by the Circle Founder. |
| Observational Protocol | One or more Case Report Forms applied longitudinally against any Case to derive real-world data and/or evidence. |

| | |
|---|---|
| Outlier Alerts | A User can receive an automatic Alert when an Observational Protocol score is above or below a pre-defined range. This may lead to a review of the most recent OP data, a communication with a patient, or other action. |
| Patient | The individual against which an observational protocol is assigned -- , pre-, peri or post therapeutically -- thus creating a Case. |
| Patient Report | A report based on data collected against one or more Case Report Forms, accessible through a patient-specific on-line portal, accessible on any mobile or desktop device. |
| Query | A Query solicits an observation determined to be essential within one or more Observational Protocols, thereby allowing statistically meaningful correlations to be established. Queries automatically conform observations to an "essential truth", even though those observations may have been recorded in different languages, units of measurements, and more |
| Scoring | Converts Query responses into integers, allowing for Case Report Forms to generate standardized and quantifiable results |
| Sponsor | The individual or entity financially responsible for payment for Cases, User subscriptions and other inCytes™-related charges. |
| Subscription | The month-to-month User access to the inCytes™ platform. |
| Team | One or more Users which are allowed to view patient health information with respect to one or more assigned Cases, as well as enter data on Case Report Forms for such Cases. |
| User | A healthcare professional or her/his delegate who has subscribed to the inCytes™ Platform. |

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