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EmpiraMed Goes Global

PRO Portal Fully Internationalized

Maynard, MA — November 12, 2019 — EmpiraMed, Inc., a leader in the field of virtual registries for Real World Evidence, today announced that their flagship product, the PRO Portal™ Software Platform, has been fully internationalized.

"We are pleased to release our newest version that allows the biotech, pharmaceutical, and medical device industries to deploy the world's leading virtual registry RWE platform to foreign countries with GDPR-compliant dynamic language support and rules-based localization for region-specific patient incentives," said Greg Erman, President & CEO of EmpiraMed.

According to Cord Awtry, VP of Engineering at EmpiraMed, "our innovative technology was designed from the ground-up to be configurable, flexible, and scalable. We extended that model to internationalization by implementing a modern, rules-based methodology to support our customers abroad."

EmpiraMed's technology was designed to be HIPAA compliant throughout, including encryption of all PHI, a fully configurable roles-based permission model, utilization of comprehensive logging and auditing of all Portal activities, and implementation of clinically rigorous patient consent workflows and methods. We have extended our system to meet GDPR requirements internationally.

New languages can be implemented rapidly using the rules engine and validated as needed. Languages are dynamically displayed according to the specific users' preferences independent of localization of the Rewards Program by geographical region. In other words, local currencies and rules can be configured separately from local languages and local languages are automatically displayed based on user preferences. Different patient groups can have different user experiences within the same study or project with respect to language, currency, eGifts, redemption rules, and other study parameters.

New features in EmpiraMed's latest release of the PRO Portal (v2019.4) include:

1. Globalization
    1.1. The Portal has been internationalized ("i18n") to support any Left-to-Right ("LTR") language including all Western European languages such as French, Spanish, Italian, and German
    1.2. The Portal has been localized ("l10n") which, as defined by the W3C, *refers to the adaptation of a product, application, or document content to meet the language, cultural, and other requirements of a specific target market (a locale).* The Portal now supports region-specific (or locale-specific) capabilities including:
        1.2.1. Region-specific dialects and language formatting
        1.2.2. Local currencies
        1.2.3. Local number and date formatting
        1.2.4. Local special characters
        1.2.5. Rewards Program Regionalization via EmpiraMed Dynamic Cohort System
            1.2.5.1. Region-Specific Currency Support
            1.2.5.2. Region-Specific eGifts
            1.2.5.3. Region-Specific Rewards Rules (such as Point Activity Limits or eGift Redemption Conversion Rates)
    1.3. Language translation configuration supports either of two methods:
        1.3.1. Certified Translation (recommended approach) where Portal translation tools prepare a translation package for use by a translation service who will translate and validate the new language to insure 100% accuracy; or,
        1.3.2. Automated Translation where the entire **new** language is self-generated by the Portal which is fast and inexpensive but only about 98% accurate
    1.4. Language translation execution has been fully automated through the EmpiraMed *Dynamic Locale Addition* to improve execution accuracy, patient ease-of-use, and to reduce global study deployment lead-time; all patient-facing text of the Portal has been extracted (externalized) to database-bound text strings and replaced by key-based tokens whereas upon rendering of a Portal patient page these tokens are replaced by the text for the selected language, default patient language as specified by the user's browser, or if none of the above then English-US
        1.4.1. Patient-facing objects include:
            1.4.1.1. All text seen by patients in the process of using the PRO Portal
            1.4.1.2. Emails
            1.4.1.3. SMS message reminders
            1.4.1.4. External documents such as the Quick Start Guide
            1.4.1.5. Localized images
    1.5. Multiple languages and localizations can be deployed in the same study or project where the Portal will automatically display the appropriate language and apply the correct localization rules on a user-by-user basis; for example, a single study could be configured where a French-speaking resident of Switzerland sees the French language

with Swiss Franc eGifts, a German-speaking resident of Switzerland sees the German language with Swiss Franc eGifts, and a resident of Germany sees the German language with Euro eGifts

1.6. Both the patient and/or Patient Recruitment Site personnel for that patient, with appropriate roles-based permission, can configure language and localization rules settings for the patient

2. Compliance

2.1. General Data Protection Regulation 2016/679 (GDPR) Compliance
2.2. International Compliance Practices Overseen by Goodwin Procter LLP

3. SMS Support; Send text messages (Short Messaging System or "SMS") to patients similar to current email reminders

3.1. Email reminders will continue to be supported

3.2. Supported SMS notifications are:

3.2.1. Survey Availability Reminder
3.2.2. Additional Survey Reminders
3.2.3. Survey Expiration Reminder
3.2.4. Other SMS reminders, such as adherence reminders for a Quality Improvement project can be configured on a custom basis

3.3. Ability for patient to add their mobile phone number to the Portal for SMS alerts

3.4. Mobile phone number verification

3.5. Both the patient and/or Patient Recruitment Site personnel for that patient, with appropriate roles-based permission, can configure SMS alerts for the patient

3.6. Support patient opt-out of SMS reminders

3.7. Support for a robust SMS framework to accommodate novel test messaging workflows as needed

4. Support for Operations-User Two-Factor-Authentication ("TFA")

4.1. Ability to configure on a study-by-study basis support for Operations Users (e.g. sponsor, clinics, or other Patient Recruitment Sites) to use TFA

4.2. TFA adds an additional level of security to an account by requiring not only a user name and password but also a generated one-time password ("OTP")

4.3. Device verification ("remember me") allows the user to apply the OTP only once so that additional logins won't require repeated application of TFA unless a configurable period of time has elapsed or other security measures are required

4.4. Support for TFA via either SMS or Google Authenticator app

4.5. Rules-based and role-based security allows configuration of TFA on a permissioned role-by-role basis

5. Maintenance Enhancements

5.1. Overhaul of EmpiraMed Rules Engine to support *New Features* above, improve rules configuration ease-of-use with no programming required, and to enhance auditing capability of study-specific rules

5.2. Expansion of the EmpiraMed Dynamic Cohort System to support *New Features*

5.3. The core software platform has been upgraded to JAVA-8 to add new security features and to maintain support by third parties

About EmpiraMed

EmpiraMed has created a novel ***virtual registry platform*** to generate ***Real World Evidence***. We have developed three products. The EmpiraMed™ PRO Portal™ Software Platform is a patient engagement system that offers unsurpassed user "stickiness" to directly capture real world patient experience. Combining our fully automated study execution rules-engine, novel patient recruitment methods, and true mobile device independence, EmpiraMed delivers the most robust Virtual Trial and Registry solution available. Non-interventional studies typically suffer from poor patient participation, so our portal includes a ground-breaking Rewards Program that has improved patient engagement to more than 3X current industry standards. Consequently, our customers have seen dramatic increases in patient participation, compliance, wearable device utilization, and overall study success. To support Post Market Required Phase IV Studies, EmpiraMed has developed the PMR Portal™ patient medical record system to capture clinic routine care data while substantially reducing clinic burden and contracting. The PMR Portal directly addresses a common problem of poor clinic participation in regulatory-agency-mandated studies. We also offer an EDC for clinic study-specific data called the MED Portal™ platform. These three products have been used to perform Observational Studies for CER, Medical Affairs, and HEOR; PMR Phase IV Studies, Safety Studies, and REMS; Drug and Disease Registries including Rare Disease Registries; Outcomes Based Contracting Programs that go beyond just claims data; and, Quality Improvement Intervention Projects to improve medication adherence. EmpiraMed's software and services support all industry compliance requirements including HIPAA, GDPR, 21 CFR Part 11, and GCP. Studies can be internationalized using our automated, rules-based, localization system. Global leaders have been using EmpiraMed's technology in a wide variety of therapeutic areas since 2011, and our customers have included prominent biopharmaceutical manufacturers such as ***Merck Sharp & Dohme***, ***Biogen***, ***Janssen***, ***Sanofi Genzyme***, ***United Therapeutics***, ***Teva***, *and* ***Takeda***. Please visit http://www.EmpiraMed.com for more information.

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