Big Data, Internet of Things, Apps: quali implicazioni per il mondo del farmaco e il settore salute

26 Novembre 2016 ore 10,00

Può un' APP aumentare il reclutamento ed il mantenimento dei pazienti in uno studio clinico?

(May an App enhance patient recruitment and retain?)

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EryDel
INNOVATION INTO BLOOD

Disclaimer

I am an employee of Erydel S.P.A.

This presentation and the concepts expressed in it, reflect the views of the author and should not be construed to represent Erydel's view

Need

Starting in 1994 several KOL started discussing about the importance of patient's compliance and adherence to treatment and study activities.
Following this very important point several Pharma companies realized the necessity to monitor compliance of patients to the treatments and to clinical trials

One of the first (1995) in this tentative has been KNOLL Pharmaceuticals who developed an electronic folder for their anti-hypertensive pill. The folder was able not only to alert the patient that was time to take the drug but also to memorize these data and discharge to the computer of the investigator.

3M too approached the same problem in a very similar way.

Other companies followed these "pioneeristic" approach, but, probably at that time the technology costs and the difficulties discouraged them

Chiesi Farmaceutici (2010)

To demonstrate the efficacy and safety of a New Chemical Entity under development for COPD Chiesi Farmaceutici in 2010 started a clinical Phase 3 trial involving for 48 weeks more than 2000 patients in 19 countries world wide.

With RIM and TechMobile support, Chiesi Farmaceutici developed an APP which aim was to administer patients a daily questionnaire to monitor the effects of the therapy and the evolution of the disease.

The simplicity and “easy to be used” BlackBerry device permitted the use by older patients too, reaching a **compliance of almost 100%.**

For this innovative approach Chiesi received the “Wireless Achievement Award”

Radboud University – NEDERLANDS (2015)

The **Parkinson@Home** Study Protocol.

BACKGROUND: Long-term management of Parkinson's disease does not reach its full potential because we lack knowledge about individual variations in clinical presentation and disease progression. Continuous and longitudinal assessments in real-life (ie, within the patients' own home environment) might fill this knowledge gap.

METHODS:
The Parkinson@Home study is a two-phase observational study involving 1000 Parkinson's patients and 250 physiotherapists.

Participants will wear a set of sensors (smartwatch, smartphone, and fall detector), and use these together with a customized smartphone app (Fox Insight), 24/7 for 3 months.
The sensors embedded within the smartwatch and fall detector may be used to estimate physical activity, tremor, sleep quality, and falls. Medication intake and fall incidents will be measured via patients' self-reports in the smartphone app.

CONCLUSIONS:
The Parkinson@Home study is expected to generate new insights into the feasibility of integrating self-collected information from wearable sensors into both daily routines and clinical practices for Parkinson's patients.

Maastricht University Medical Center, the Netherlands. (2015)

Unraveling the Relationship between Motor Symptoms, Affective States and Contextual Factors in Parkinson's Disease: A Feasibility Study of the Experience Sampling Method.

BACKGROUND:
In **Parkinson's disease** (PD), the complex relationship between motor symptoms, affective states, and contextual factors remains to be elucidated.
The **Experience Sampling Method** provides (ESM) a novel approach to this issue.

Using a mobile device with a special purpose application (app), motor symptoms, affective states and contextual factors are assessed repeatedly at random moments in the flow of daily life, yielding an intensive time series of symptoms and experience. The aim of this study was to study the feasibility of this method.

METHOD: We studied the feasibility of a **five-day period** of ESM in PD and its ability to objectify diurnal fluctuations in motor symptom severity and their relation with affect and contextual factors in five PD patients with motor fluctuations.

RESULTS: Participants achieved **a high compliance, with 84% of assessment** moments completed without disturbance of daily activities.
The utility of the device was rated 8 on a 10-point scale. We were able to capture extensive diurnal fluctuations that were not revealed by routine clinical assessment. In addition, we were able to detect clinically relevant associations between motor symptoms, emotional fluctuations and contextual factors at an intra-individual level.

CONCLUSIONS: ESM represents a viable and novel approach to elucidate relationships between motor symptoms, affective states and contextual factors at the level of individual subjects. ESM holds promise for clinical practice and scientific research.

Roche

Roche Pharma Research & Early Development (pRED) has developed a smartphone-based monitoring system for those with Parkinson's disease (PD) that complements the traditional physician-led assessments with automated tests that continuously measure their symptom fluctuations.

In clinical trials in this area, disease disability and impairment are traditionally measured by physician assessments using the Unified Parkinson's Disease Rating Scale (UPDRS). However, these are limited to the specific times that patients go for an appointment with their physicians.

The app will enable continuous measurement of Parkinson fluctuation **every day and throughout the day**.

Patients will be asked to follow a daily routine with the app, using it every day for the duration of the trial.

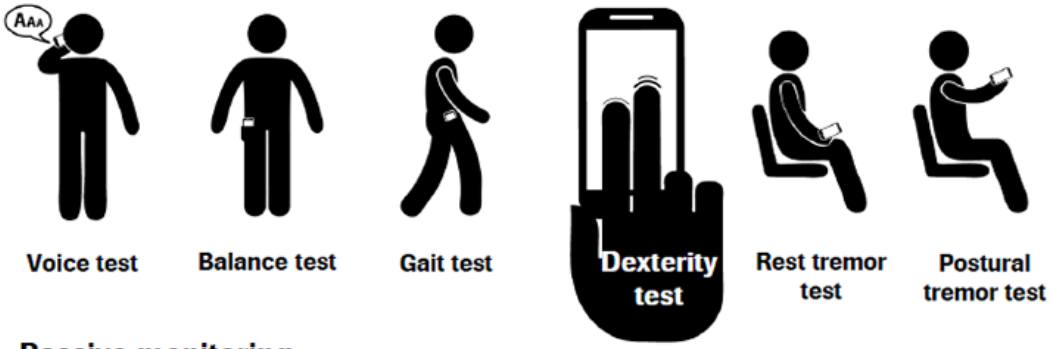
For Active Monitoring the patients will be requested to preform some simple activities.

For passive monitoring, patients are asked to carry the smartphone with them throughout the day. Data is then collected from the various smartphone sensors. Patients will be asked to use the app for the duration of the trial, including screening, dosing and follow-up, which may last up to a period of about 32 weeks.

Roche provides patients with dedicated, preconfigured smartphones for the sole purpose of remote patient monitoring via the app. This makes the device and the app easier to use for the elderly patient population.

Active tests

Patients complete six tests on the App at the same time each day



Passive monitoring

Patients carry the phone around all day as they go about their daily activities

Passive monitoring

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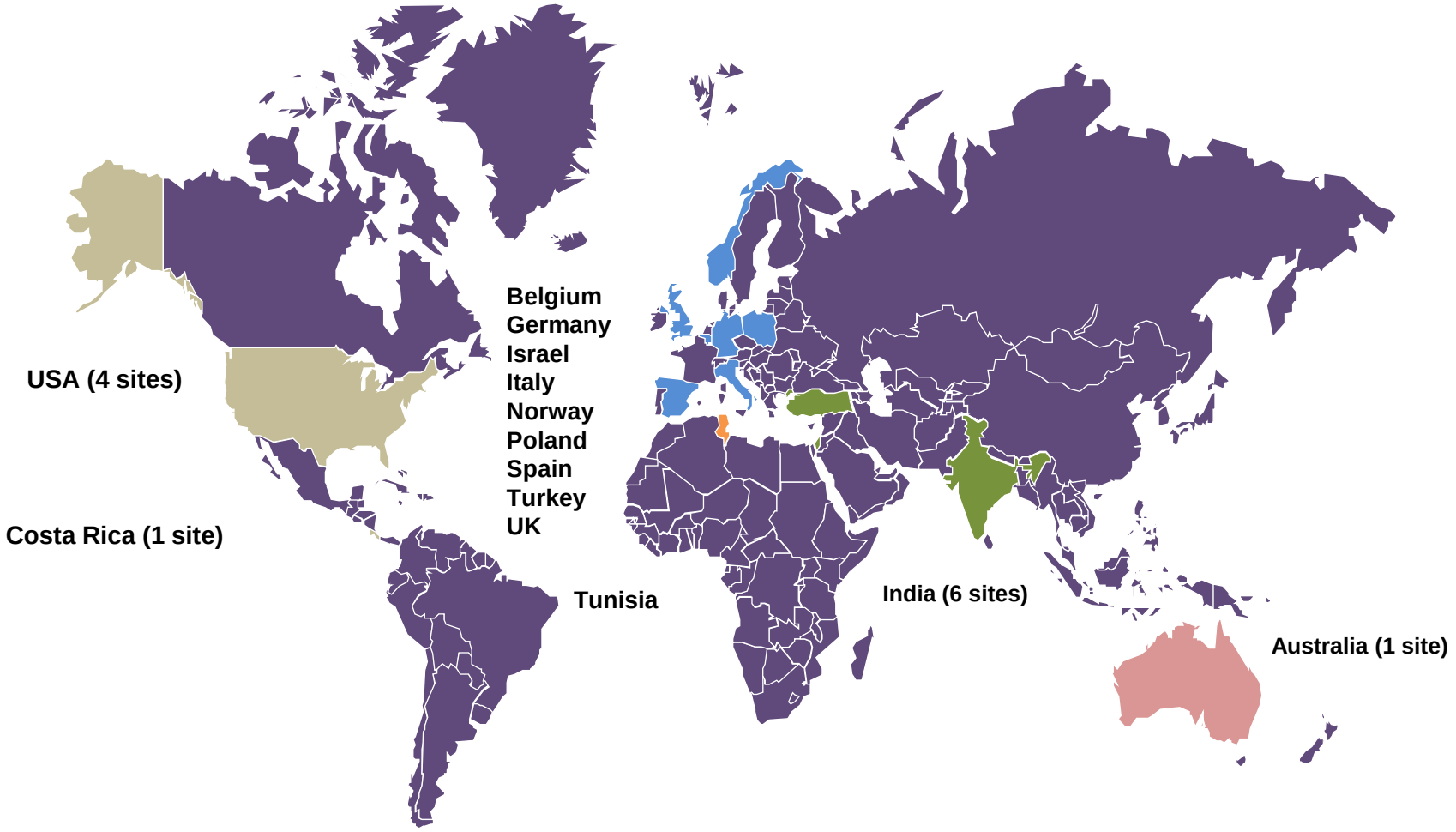
- Biotechnology company focused on the development of drugs and diagnostics delivered through erythrocytes
- Leader in autologous erythrocyte technology
- Focus on orphan indications
- Based on innovative Platform technology
- Horizon 2020 European Grant

Phase 3 WW pivotal trial



Phase 3 WW pivotal trial

More than 200 pts randomized

Different countries

Several travels of children with high degree of disability and one caregiver

Global strategy to manage triavels to the sites and accomodations

patient primary

EryDel AT Study





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The problem – patient drop-outs

Recruitment cost

Time consuming

Delays to trials

Trial data

Patient travel flow chart

Our apps

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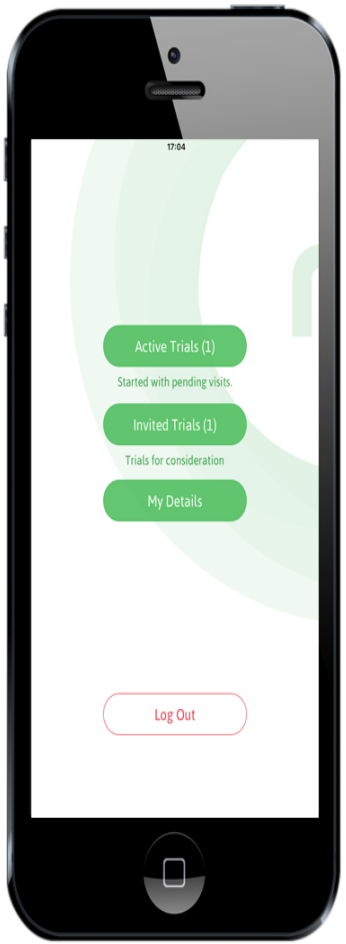
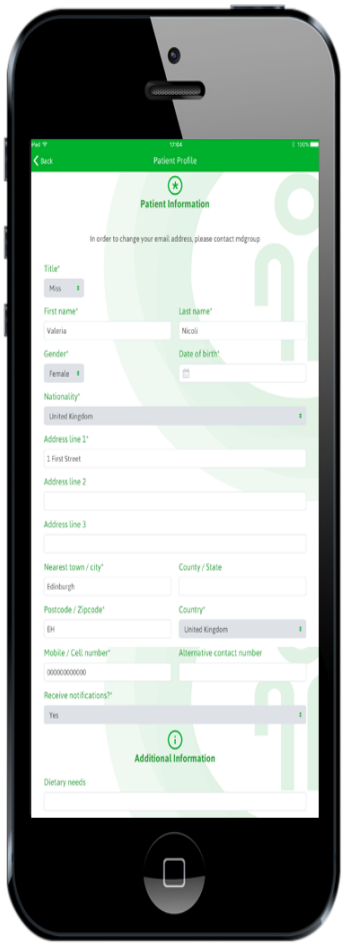
patient primary

- iOS and Android
- Multi-language
- Appointment, travel dates
- Issue alerts and updates
- Secure password/PIN access

Login



Landing page



Patient information

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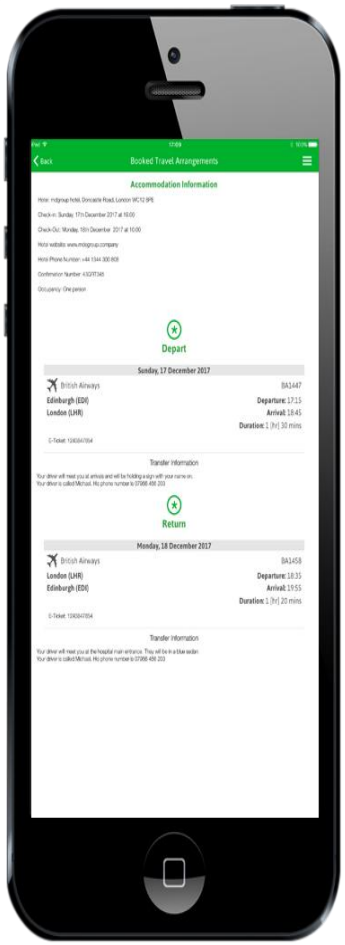
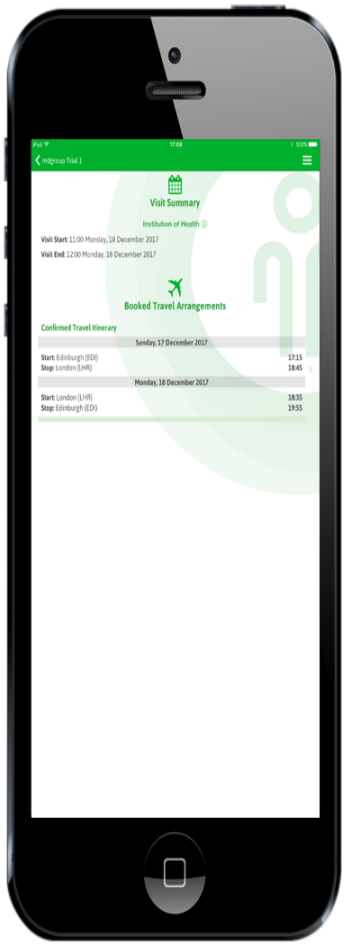
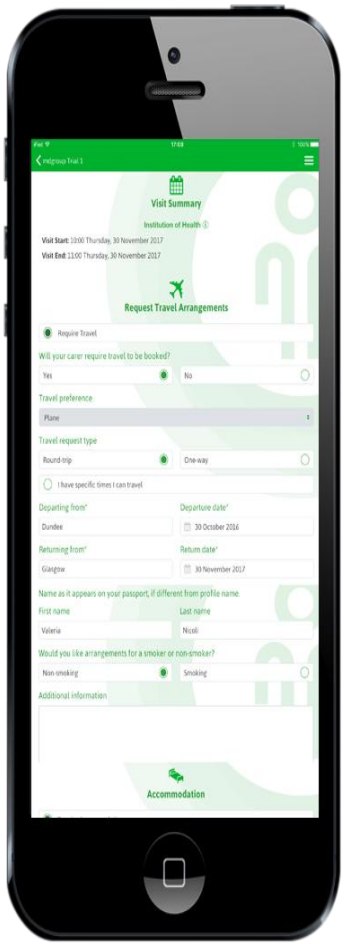
patient primary



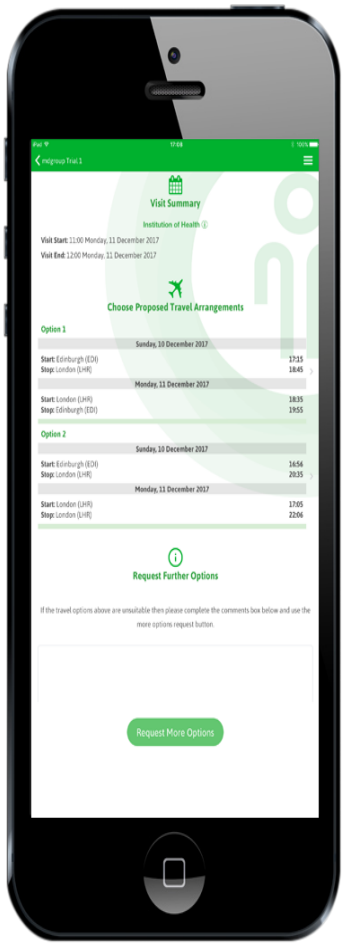
Travel booked summary



Travel booked



Travel booking – filled out



Travel options

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expense first

- Fast, efficient, compliant expense management
- Receipt upload
- Legitimacy check
- Pre-issued post-load card system
- Avoids bank charges
- Straightforward for user
- Worldwide acceptance
- Any ATM withdrawal
- Tracking
- Ethical and transparent
- Payment tracking

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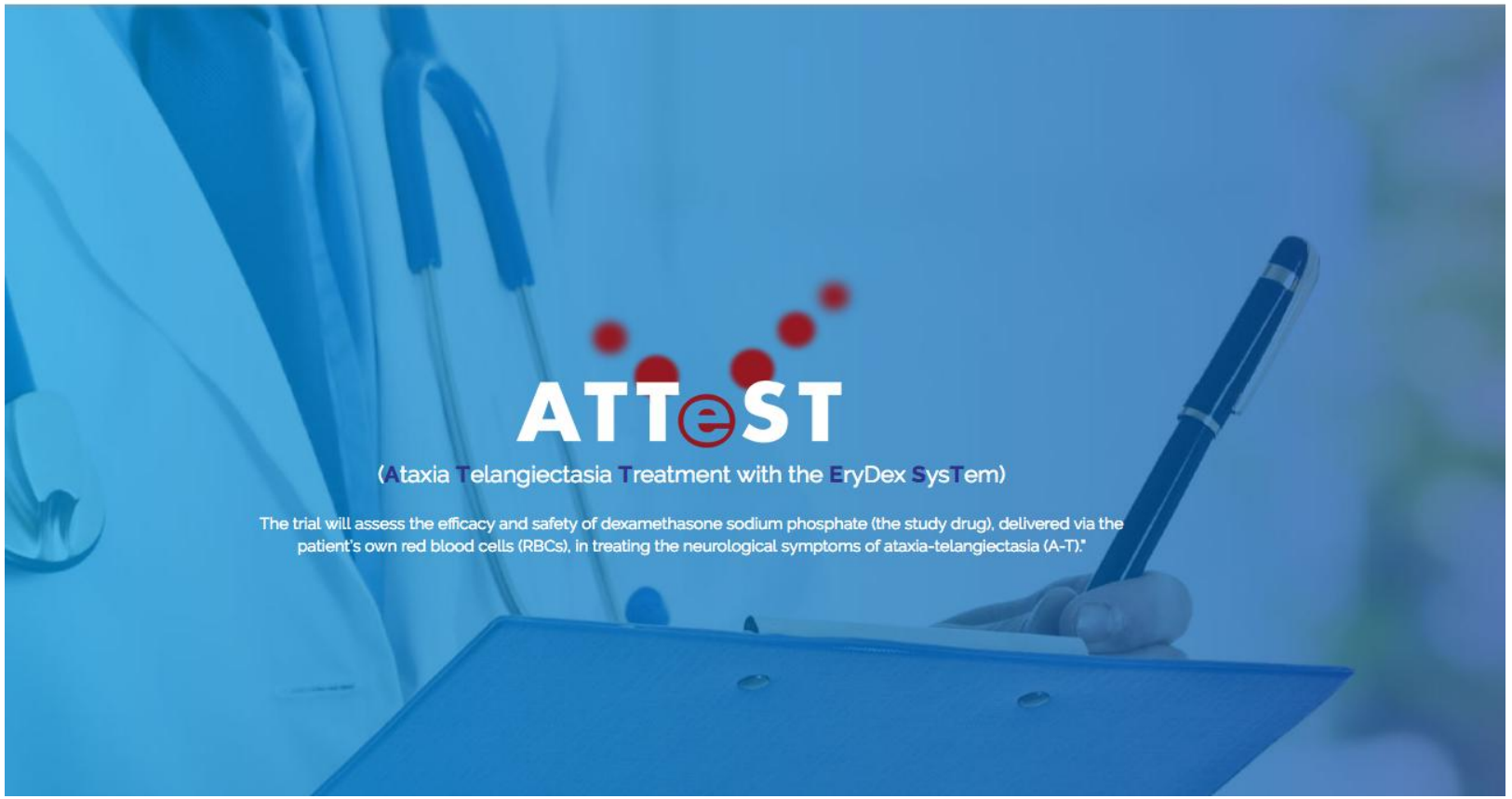
http://attest-trial.com/

An invaluable tool for patients and families



Live soon!!!

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Thank you

…help us in giving Children a chance

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