

## CSI INNOVATION – CALL FOR IDEAS 2017

1. **Full title of the research proposal:** Tailoring Oral therapy in Rheumatic Diseases: the “TuTOR study”
2. **Submitted by:** Prof. Dario Roccatello: MD. Center of Research on Immunopathology and Rare Diseases (CMID), San Giovanni Hospital, Torino and University of Torino, Italy. Full Professor at University of Torino, IT

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3. **Project Area:** Health

4. **Summary**

Medication adherence is crucial for a successful management of patients with chronic conditions, such as rheumatic diseases (RD). Shifting medications, polypharmacy and complexities of daily life are likely to contribute to patients’ inability to deal adequately with their medical conditions. Indeed, with respect to important risk factors of RD such as cardiovascular risk factors it is known that up to 50% of patients will stop taking medication for these conditions during the first year of prescription.

This study aims to analyze whether a mobile application on a tablet or Smartphone aimed to support drug intake and disease activity parameter documentation affects adherence in RD patients.

In detail, we aim to develop a mobile application to support the therapy management of RD patients treated with chronic therapies to improve their therapy adherence (TuTOR mobile App). This study will evaluate the effect on participants’ reported adherence to medication and to protocol laboratory and clinical follow-up. Adherence to therapy will be evaluated through objective information acquired from the logged interaction protocols and users’ subjective assessments and quality of life questionnaires that will be provided in the first visit and follow-up visits.

In addition, the influence on affinity for technology will be evaluated in order to determine if particular subgroups of RD patients will be more indicated for the use of the mobile application.

Fifty patients with RD treated with chronic therapies will be recruited. They will receive a personal introduction to the mobile application TuTOR mobile App, installed on a tablet or Smartphone. The study will be conducted using a crossover-design with 3 sequences: initial phase, interventional phase (3 months of using the app system), and comparative phase (3 months using a paper diary). Users will experience the interventional and comparative phases alternately.

We anticipate that the mean for subjectively assessed adherence will be more pronounced after the interventional phase than after the comparative phase. Similarly, a better adherence would in an adequate control of disease activity.

From a speculative point of view, in the future the information collected via TuTOR-App might be linked to the e-record of the patient, the so called *Fascicolo Sanitario Elettronico*, providing further tools to the treating physicians when assessing disease progression, allowing to check for therapy adherence before considering any change in the management. Similarly, when information on adherence will be available, they might help to tailor diagnostic-therapeutic pathways (the so called *Percorsi Assistenziali di Cura*), e.g. identifying specific strategies for patients with poor compliance, in order to improve the overall management of chronic conditions.

5. **Project Impact and future developments:** (150 W)

A mobile app for medication adherence might increase objectively and subjectively measured adherence in 50 RD patients with chronic therapy. The findings might have promising clinical implications: digital tools can assist chronic disease patients achieve adherence to medication, leading to a better disease management. Ideally, it can reduce complications and clinical overload because of non-adherence. Telemedicine is an emerging new area in patient care, offering new tools and providing clinical health care from a distance. Telemedicine supports in-home care and has been used to overcome distance barriers and to improve access to medical services that would often not be consistently available. In this new setting, the TuTOR-App, might be able to widen Telemedicine technologies, permitting

communications between clinicians and the patient, as well as the transmission of therapeutic adherence data and health informatics data from one site to another, allowing data analysis of relevant health-related information of the patient.

## 6. **Project Details:**

- **Objectives:** In this project, we aim to develop a mobile application to support the therapy management of RD patients treated with chronic therapies to improve their therapy adherence (TuTOR mobile App). This study will evaluate the effect on participants' reported adherence to medication and to protocol laboratory and clinical follow-up. Adherence to therapy will be evaluated through objective information acquired from the logged interaction protocols and users' subjective assessments and quality of life questionnaires. In addition, the influence on affinity for technology will be evaluated in order to determine if particular subgroups of RD patients will be more indicated for the use of the mobile application.

### **-Proposed research protocol**

#### TuTOR mobile App development:

The TuTOR mobile App will be designed to help patients to improve adherence to self-management, clinical follow-up and medication. The TuTOR mobile App will be compatible for iOS and Android. All of the materials will be available in English and Italian (the native language of the participants).

#### Medical Plan

In this form, the patient will find all listed medications that is currently taking. Information provided will be: name of the medication, number of intakes per day, and corresponding doses. The patient won't be able to change the list of medications, only the investigator of the study will be provided with the code to change the "Medical Plan" settings. The patients will have to check the boxes each day when taking every medication suggested by the TuTOR mobile App with the possibility to recover a wrong information if given a wrong input.

#### Clinical Follow-up

In this form, the patient will find all planned follow-up clinical appointments according to the treating clinician indications. Information provided will be: follow-up visits (date, time, location and name of the reference Doctor of the center), specialist appointments (date, time, location and name of the Specialist Doctor), instrumental testing (date, time and location) and laboratory testing (date, time and location). The patient won't be able to change the planned follow-up list, only the investigator of the study will be provided with the code to change the "Clinical Follow-up" settings. The patients will have to check the boxes for each follow-up visit performed suggested by the TuTOR mobile App with the possibility to recover a wrong information if given a wrong input.

#### First Visit:

The patients will be introduced to the TuTOR mobile App service with a learning-by-doing tutorial session. The participants will be familiarized with the functions of the application (i.e., confirming medication intake and recording follow-up visits and clinical appointments) and how to recover if a wrong input had been made.

The participants will complete the questionnaires on technical knowledge and experience and the questionnaires on subjective adherence. All of the materials will be in English and Italian (the native language of the participants).

After the participants completed the initial tutoring and questionnaires, the examiner will introduce in the TuTOR App "Medication Plan" all listed medications presently prescribed on a prepared form, based on the patients' clinical-report. The examiner will also introduce in the TuTOR App "Clinical Follow-up" all follow-up visits, specialist appointments, instrumental testing and laboratory testing according to the treating clinician indications. The following data will be recorded: name of the medication, number of intakes per day, and corresponding doses, follow-up visits, laboratory testing, instrumental testing and specialist appointments, self-assessment status (e.g. Visual Analogue Scale).

The users also received a paper-based notepad in which they could write down any problems or particularly positive aspects (e.g., those which might have been difficult at first) they encountered when utilizing the TuTOR App. The intervention was not used in the context of a particular medical treatment, and no feedback by a doctor was given on recorded vital signs. Each of the data collection sessions will take between 1 and 2 hours.

#### Follow-up visit a month 3 and 6:

In the following follow-up visits, semi-structured interviews will be performed to assess participants' responses to using the system and to address any question or problems they might have encountered during the 3 months of using the

mobile TuTOR App. The participants will also complete questionnaires on quality of life improvement since beginning the therapy and using the TuTOR App for support. Each of the data collection sessions will take between 30 minutes and 1 hour. All of the materials will be in English and Italian, the native language of the participants.

**Outcome evaluations:** A data tracking system recording the number and length of use of the app will be put in place. Retrieved data will be analysed and compared to clinical information, laboratory profile, quality of life outcomes and questionnaires results.

Task and Milestones	Months											
	1	2	3	4	5	6	7	8	9	10	11	12
Mobile App development												
Patients recruiting, sample and clinical data collecting												
Follow-up and data collecting												
Data analysis												

### 1. Budget Plan

	Initial Budget
<b>List of Direct Labor Costs</b>	
Statistical analysis and data Mining	12.000
Data Management (to include data storage)	24.000
Publication costs	3.000
App development	20.000
subtotal	59.000 €
<b>List of Direct Study Costs</b>	
50 first visits with tutorial sessions (2h/visit/physician)*	10.000
100 follow-up visits (1h/visit/physician)*	20.000
Estimated insurance costs for 50 patients	50.000
subtotal	80.000€
<b>Institutional overhead costs</b>	
10% of the total	13.900€
<b>TOTAL</b>	152.900€

\*as estimated according to deputy office for International Grant Application, University of Torino.