

THE CAPRI PROGRAM PROVES ITS CLINICAL AND ECONOMIC EFFICIENCY for personalized remote monitoring of patients treated with oral anticancer drugs

The results of the prospective study, presented at the ASCO 2020 conference, which is taking place virtually this year due to the Covid pandemic, provide for the first time scientific evidence that a system combining digital technology and new human organization, significantly improves the clinical follow-up of patients treated with oral anticancer therapies. The innovative Capri digital solution was launched by researchers at Gustave Roussy in 2015.

The study has demonstrated its ability to reduce treatment-induced severe toxicities, which can sometimes require reducing or interrupting treatments, and to decrease both the number and the duration of hospitalizations related to these toxicities. Patients also reported very positive feedback from their experience. Based on these findings, the CAPRI system should be considered as a new standard of care for monitoring oral therapies in oncology. The study will also be presented in the ASCO “Highlights of the day” for which the top 3-4 most important abstracts of the day are selected (according to disease/topic).

The use of oral anticancer drugs (OADs) is rapidly increasing. Since 2000 more than 50 new marketing authorisations have been granted for oral drugs. In several cancers, OADs are standard treatment, even for initial/first-line therapy. OADs are more convenient since they can be picked up at community pharmacies, and patients do not have to go to hospital as frequently as they would for intravenous treatments. Nevertheless, the use of OADs raise a number of issues. It is common practice to monitor early side effects during a visit scheduled 2-3 weeks after initiation of therapy, but *“apart from the routine three-monthly visits to the oncologist, no clear scientific recommendation exists to guide the appropriate frequency of monitoring of patients on oral treatment,”* explained Dr. Olivier Mir, medical oncologist at Gustave Roussy, and principal investigator for the study.

Indeed, in practice, OADs cause a broad range of adverse effects. *“The problem is that these occur at home. Given the multiplicity of agents on the market, neither general practitioners nor dispensing pharmacists are prepared to manage them,”* emphasized Dr. Mir.

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Oral presentation
by Dr. Olivier Mir

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There are no clear scientific recommendation to guide the appropriate frequency of monitoring of patients on oral treatment though side effects occur at home.

If these are not treated promptly, the risk of serious toxicity is increased, sometimes resulting in hospital admission, and even more frequently in reduction in dose or cessation of administration of the agent. Although the dose and number of effective intakes (dose intensity) of the drug actually received by the patient (relative dose intensity or RDI is the difference between the dose originally prescribed and the dose actually received by the patient) is a major element in oncology, ***“previous studies estimate that this relative dose intensity does not exceed 85% for oral anti-cancer drugs,” explained Dr. Mir.*** That means that 15% of patients on oral drugs temporarily suspend their medication or have to reduce doses thought to be necessary to treat their cancer.

Reducing this risk arising from side effects and increasing the RDI value by closer monitoring of outpatients receiving OADs constitutes the entire purpose of the CAPRI program. The strength of the program and of its evaluation is to focus on ***“real-life patients, treated with drugs which are already on the market,” insisted Dr. Mir.*** Better drug tolerance, a reduction in severe adverse events and hospital admissions and improved patient experience: the randomised phase III clinical study presented as an oral communication at ASCO 2020 shows that the innovative system of personalised telemonitoring developed from research conducted at Gustave Roussy, fulfils these objectives. By delivering marked added value in all these aspects ***“CAPRI facilitates the development of a genuine clinical relationship at a distance,” summarised Professor Etienne Minvielle,*** physician and researcher in management at the Ecole Polytechnique and Gustave Roussy, scientist in charge of the project since its inception.

CAPRI (acronym of CAncérologie, Parcours, Région, Ile de France – Oncology Pathway in the Ile de France Region) is a research project carried out at Gustave Roussy since 2015 with support from Fondation Philanthropia, a leading sponsor of the hospital. ***“At the time,” remembered Etienne Minvielle, “the subject seemed to be entirely exploratory.”*** It was a challenge to conceive of an effective system. ***“At one time we considered the possibility of giving each patient a tablet computer allowing direct communication with the consultant physician,” explained Professor Minvielle. “But that proved unsatisfactory. Patients raised many queries which were perfectly legitimate but did not require the multiple medical skills of an oncologist.”*** There was a paucity of useful material in the scientific literature. ***“Most of the publications were about telemonitoring in cardiology or diabetology and the only oncological one was devoted to the follow-up of symptoms of lung cancer. There were none on oral anti-cancer agents,” summarized Olivier Mir.*** Those telemonitoring initiatives embarked on locally, many of them instituted by start-ups, ***“involving either inadequate numbers of patients or a limited range of cancers, or assessment without a comparative arm,”*** did not yield results that allowed definitive conclusions to be drawn either on the effectiveness of the systems or on the ideal methods to be employed.

CAPRI telemonitoring went operational in 2016. It is based on three elements, the most important one being the personal. ***“This is our great premise,” declared Professor Minvielle, “a technological operation can only function if it is combined with a human approach.”*** Thus the team is composed of two coordinating nurses, specially trained in this new role of oncology support.

An initial interview to enrol the patient follows the consultation during which an OAD has been prescribed. During this interview, more detail is added to the information given by the oncologist on prevention and management of possible side effects. The digital CAPRI interface (internet platform and mobile app) is accessible to assigned outpatient health-care professionals (general practitioner, pharmacist and district nurses) who are thereby enabled to visualise and record all of their consultations. Medical reports, contact details of the health care staff involved, and a broad spectrum of validated medical information on the patient’s disease, its treatment and its effects are also accessible.

In particular, this allows the patient to communicate at any time any information relevant to monitoring of the treatment - questions or worries - to the nurse navigators, who can also be contacted on a dedicated phone line.



CAPRI Program :
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severe toxicities
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“The rationale,” insisted Olivier Mir, “is not in any way that they represent just another participant in the patient care pathway,” but act as a genuine resource the patient can rely on. In addition, they ensure that the patient’s general condition is monitored regularly by telephone or encrypted message service as frequently as scheduled in the program. In the context of the research study, this was established as weekly follow-up for 6 weeks, followed by gradual increases in the intervals. In all cases, at each contact with the patient, the nurse completes a digital intervention form. At the least alert, she consults the decisional tree provided by the program: a series of algorithms designed to determine the action that has to be taken for each problematic situation (and in the presence of each symptom), according to the severity or seriousness and to the patient’s condition. ***“Not all adverse events, except for those of grade 3 severity, which would necessitate cessation of therapy, require the involvement of the treating oncologist,”*** emphasized Olivier Mir. According to the first reports of the study results at the ESMO Congress in 2019, in 75% of cases the coordinating nurses were capable of responding on their own to the patient’s needs. They were able to anticipate complex clinical situations, with significant improvement in patients’ outcomes, as confirmed by the data presented to ASCO this year. To evaluate the program, 609 patients with every type of metastatic cancer were recruited between 2016 and 2019, excluding those already enrolled in another clinical trial. All were taking an OAD in the form of targeted therapy or chemotherapy, with only those exclusively on hormone therapy being excluded. 47% of them had previously received two or more previous lines of treatment. 41% were over the age of 65. Half of the study patients had Capri telemonitoring in addition to conventional monitoring by their consultant oncologist. The primary objective of the study focused on the relative dose intensity (RDI) at six months. At this point, the relative dose intensity was significantly higher in the CAPRI arm (93.4%) than in the “standard follow-up” group (89.4%). The program also improved the patient-experience (the usefulness of the intervention being measured by the PACIC score). Grade 3-4 adverse events (the most severe) were less frequent (27.6% vs. 36.9%). The number of hospital admissions during oral medication was lower in the CAPRI group (15.1% vs. 22%), and so was the duration of hospitalizations (mean of 2.82 vs. 4.44 days).

While progress in oral anti-cancer medication is continuing, all patients receiving it should now be eligible for a similar monitoring tool. The scientific reliability of the evaluation performed for this project and its findings ***“mean that this can be applied as a new standard for monitoring oral anti-cancer treatments,”*** declared Dr. Mir. None of the patients enrolled in the Gustave Roussy study were “lost to follow-up”. Although 41% were older than 65 and 14% older than 75, age did not prove to be a problem in use of a digital platform. ***“Provided that funding is forthcoming for structuring the tool on a human scale and for training oncology nurses in this new role, the system is perfectly transferable to any cancer treatment centre,”*** emphasized Dr. Mir. Some interested hospitals, having heard of the trial, have already contacted Gustave Roussy to tap its expertise. The programme has also shown itself to be suitable for other situations requiring telemonitoring at home: Gustave Roussy demonstrated this by adapting it rapidly into the CAPRI-Covid app, in order to supervise and advise in their homes patients infected with the coronavirus and, in particular, offer support for expressed psychosocial fragility.

The Cancer Institute is now already concentrating on a CAPRI-2 objective. ***“Together with our teams, we have already thought about researching dedicated cohorts to explore specific cancers subtypes or recent classes of oral anticancer drugs, and looking further into patients’ adherence to the treatment.”*** specified Dr. Mir. In the future, CAPRI might also be developed and assessed in long-term oral treatment situations such as hormone therapy. This is prescribed in prostate cancer, and for at least 5 years in some breast cancers, and can also cause significant side effects sometimes leading patients to discontinue it.

Regarding Gustave Roussy

Gustave Roussy, the leading cancer center in Europe, is a comprehensive hub of expertise in oncology, entirely devoted to patients. It employs 3,100 professional staff engaged in patient care, research and teaching.



A new standard for the monitoring of patients on oral medication.

CAPRI is easily transferable to any cancer treatment centre.

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