The CAPRI trial

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CAncerologie, Parcours de soins, Région Ile de France :
Impacts d'un dispositif de suivi à distance des patients traités par thérapeutiques orales

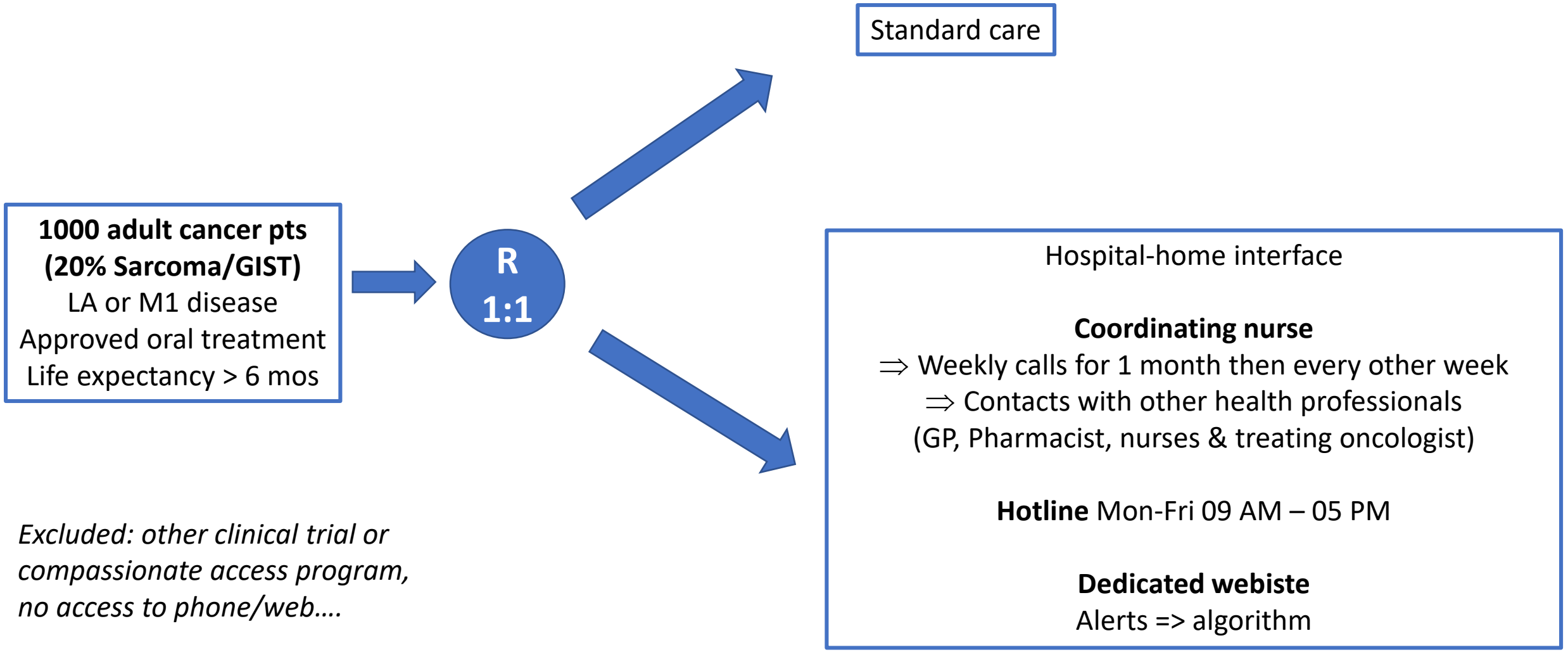
Etude randomisée

Acronyme: CAPRI

Version n° 1.0 du 14/03/2016

Gustave Roussy
114 rue Edouard Vaillant
94 805 Villejuif
France

Study design



Excluded: other clinical trial or compassionate access program, no access to phone/web….

- **Primary judgement criterion:** relative dose-intensity @ 6 mos

  Hypothesis: increase by +5% (85 => 90%)

- **Secondary criteria:**
  - Observance (Moriski questionnaire, MEMs)
  - Grade 3-4 toxicity (NCI-CTCAE v4.03)
  - QoL: QLQ-C30 (@ visits 0, 3, 6)
  - Patient’s experience: PACIC questionnaire (@ visit 6)
  - Medico-economic analysis
  - RR, PFS, OS

a. The MEMS® cap and MEMS® reader

MEMS® caps, "Medication Event Monitoring System", record the date and time of each opening of the vial and is capable of storing up to 3800 medication events. A version of the MEMS® has a LCD display which shows the number of openings during the current 24 hr period and time elapsed since the last opening.

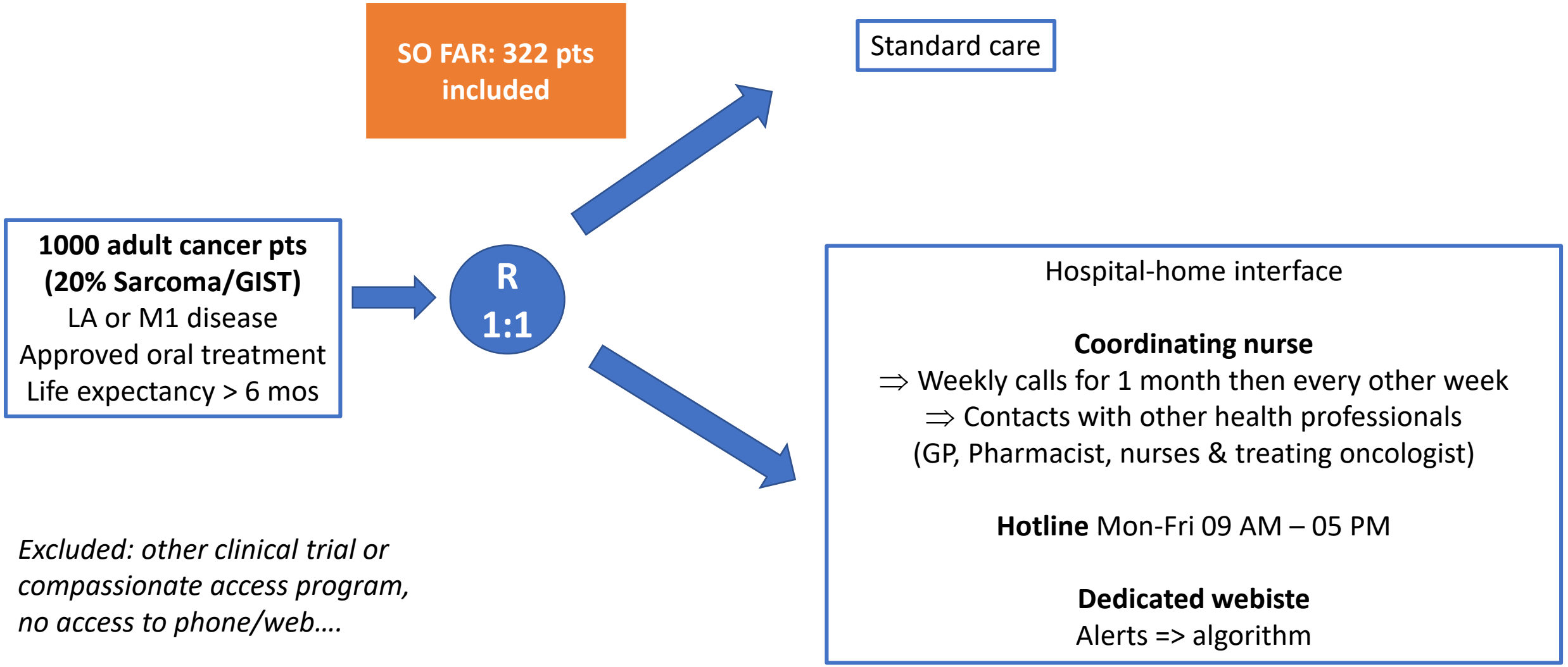
The MEMS® Reader allows the transfer of data registered in the MEMS® monitor onto a secured server via a secured web platform.

Figure 1: MEMS® caps, MEMS® caps with LCD and MEMS® reader.

b. medAmigo

The medAmigo web platform is an online web-solution to retrieve and transfer dosing history data from the MEMS® or MEMS-compatible monitors through the internet to dedicated servers. The dosing history data are stored on centralized, secured servers and regular backups are scheduled. Assuming that you have an Internet connection, you can download and/or visualize MEMS data from anywhere. The data are securely transferred and stored encrypted on our servers.

Study design



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