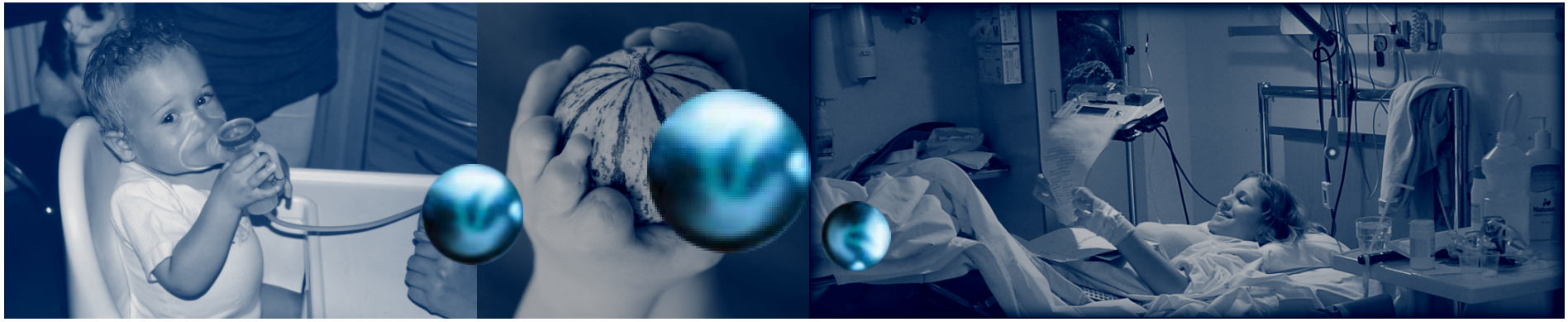
# Off-Label Medicines Use

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# Preliminary Results

1. Presentation by Rob Camp at the European Medicines Agency (EMA) at the Patient and Consumer Working Party (PCWP) including Health Professionals in Sept 2012. Also presented to Council of National Alliances and Council of European Federations – Oct/Nov 2012.
2. The Drug Information, Transparency and Access Task Force (DITA) of Eurordis would like to work on the follow matters.
3. To produce a report for publication of the preliminary results in a journal to keep the importance of “off label” use in “the public eye”.

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# What other plans

4. To produce off label webinars in all survey languages. To share results with everyone that filled in the survey. These webinars will be open to people who haven't yet filled in a survey, in order to show them how important it would be to add their information to what we already have.

5. To refine the questions as they currently are, for example separating the question of access from the question of supply.

6. To try and expand the number of languages – currently we have English, French, German, Italian and Spanish. Do we need other languages – Polish or Russian? To expand to reach 2500 patients in the next survey. A tenfold increase.

# Educating Patients/Public

7. To  make sure when taking medication - a patient is aware that they maybe taking that medication off label. 93% of rare disease patients take a medication off label.

8. To inform the public that anyone of them may need to take an off label medicine at some point in their lives.

9. Our goal is not to hinder/slow the process of using off label medications but to make it more transparent - to help the patient understand what is and what is not known about the medication they are taking. To generate interest that we need to gather information about efficacy and safety when medicines are used off label.

# Responsibility

10. Do we need confirmatory trials or data in new indications or simply clearer information about the medicine?

11.Making the responsibility lines clearer – does an informed consent need to be signed by the patient?

12. Does the patient (and the Doctor) know who is responsible in case of bad reactions and results?

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# What else could we do?

13. Properly recording the results of off label use, with information of medicines, diseases and side effects going into a database.

14. A version of the survey to health professionals (including nurses). How can a patient better understand and take advantage of the process.

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