When the trial you need is just over the border

Kathy Redmond ■ EDITOR

The bureaucratic obstacles that often prevent European cancer patients from joining clinical trials in other Member States came under the spotlight recently in the case of a young woman with melanoma. Belgian-based Patricia Garcia-Prieto has stage IV melanoma which is positive for the BRAF V600 mutation. When her disease started to advance she decided her best chance of living longer, with a better quality of life, lay in joining a phase III trial with PLX 4032 that is running in France. Her oncologist agreed that this would be her best option, and the French investigators deemed her eligible for the trial.

The trial does not require hospitalisation and the only costs that her Belgian insurers would have to cover would be some follow-up tests (such as PET scans and MRIs). All she needed from her insurers was an E-112 form – the EU administrative mechanism that gives citizens access to pre-authorised care in another Member State. The insurers refused the request, however, stating that it was the patient's own personal motivation to join the trial – not a need to secure healthcare abroad. Patricia Garcia-Prieto launched a campaign to get that E-112 form, using as many contacts as possible to get the decision overturned. Her story was covered in the respected French-language newspaper *Le Soir* (http://tiny.cc/patriciastory).

As a result of concerted pressure, the insurance company gave her an E-112 form valid for three months. She started the trial on 31 March, knowing that she has only a 50% chance of receiving the trial drug PLX 4032, but happy that she has done everything in her power to give herself the best chance of living longer – a key consideration for any mother of two young children.

With European citizens becoming ever more mobile, issues surrounding their rights in relation to cross-border healthcare need urgent attention. At the end of last year there were strong hopes an agreement could be reached that would have paved the way for an EU Directive that would allow patients like Patricia to join trials in other Member States.

Unfortunately, that agreement is being held up by concerns covering a broad spectrum of issues, none of which should be impossible to resolve. These include protecting the principle of subsidiarity, definitional confusion about what constitutes hospital care, worries about clinical oversight and liability, issues surrounding patient confidentiality and lack of agreement about what can be reimbursed.

Efforts continue to clarify these outstanding concerns, and the few Member States that are stalling the process are under pressure to sign up to revised proposals. The European cancer community can contribute to the current debate by highlighting the problems patients and clinicians face in getting access to cross-border healthcare, and suggesting workable solutions that would be quick and easy to implement.