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Date: 10/02/2002 02:40:52 PM

From: CN=Anita L Johnson NONLILLY/OU=AM/O=LLY

Subject: Off-Label Strategy Workshop

Walter,

1. I do not like "off-label" term - "Elderly and new domains" maybe.
2. This is not a US priority but I would appreciate regular team updates to Rob Distefano.

Thanks,
Jill

Original e-mail from 9/25/02:

A couple of weeks ago, when we stopped the Borderline registration program, it was clear that the domain was too important to be dropped completely. Furthermore, it is important that any activity on off-label use in general gets incorporated in the organization and planning of the Global ZPX Team, i.e., in the NRT-SDD Rosetta thing. Like for Elderly we could have a small group of people working on this, setting priorities and elaborating (a very few) proposals for IITs, SNRTs, symposia, . . . Lorrie told me we could profit a lot from work done in the past.

I would propose to start with only 4 people, i.e., somebody from marketing (I think of Lorrie, who is taking over for Frances, and of Sheila),

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somebody from the US affiliate (Ginnie), and myself, who should make a short list of priorities and projects addressing these priorities. If some of the projects get 'approved' by the Rosetta committee we can evaluate if other people (e.g. CDA, stat, writer, other marketing person) should join in. Of course, if you think anybody else should join in now or is interested to help us out, that would be welcome. Through this prioritization and planning activities a better guidance can be given to IIT committees also. *The goal is to build a comprehensive strategy for off-label indications and special populations and have this strategy implemented in an organized way with the appropriate focus.*

Could you give your comments, advice, and support on this?

Walter Deberdt
Sr. Clinical Research Physician