

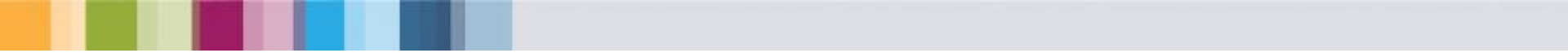


EUPATI WP7

Guidances: Public consultation

PCWP, 14 June 2016

David Haerry, co-lead WP7



GUIDANCE DOCUMENTS HISTORY

- **PCWP discussion 2008, leading to Code of Practice between patient organisations and industry (April 2009)**
- **Possible to cover only post-approval interaction, and only patients/industry**
- **EUPATI-IMI: Opportunity to complete the job**
- **Goal**
 - To provide a sound basis for meaningful, constructive and safe interaction between patients & other stakeholders
 - To reflect current thinking and legislation
 - EUPATI legacy and subject of further development

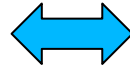
D7.2 GUIDANCE DOCUMENTS

OBJECTIVE

Create 4 frameworks to provide guidance for structured interaction on national and European level between:

Patients (representatives)

*Industry, Regulatory
Agencies, HTA, Ethics Committees*



PROCESS

- **Draft frameworks developed by WP7 in collaboration with experts from fields of interaction**
- **Activities organised to discuss and consolidate the contents of the frameworks:**
 - ✓ Industry workshop, Berlin July 2014
 - ✓ Ethics Committees Roundtable, Brussels September 2014
 - ✓ Webinar on Ethics Committees, Brussels March 2015
 - ✓ DIA Euroconference session on EUPATI, Paris 2015
 - ✓ (Upcoming) Patient/stakeholder workshop, July 20 2016

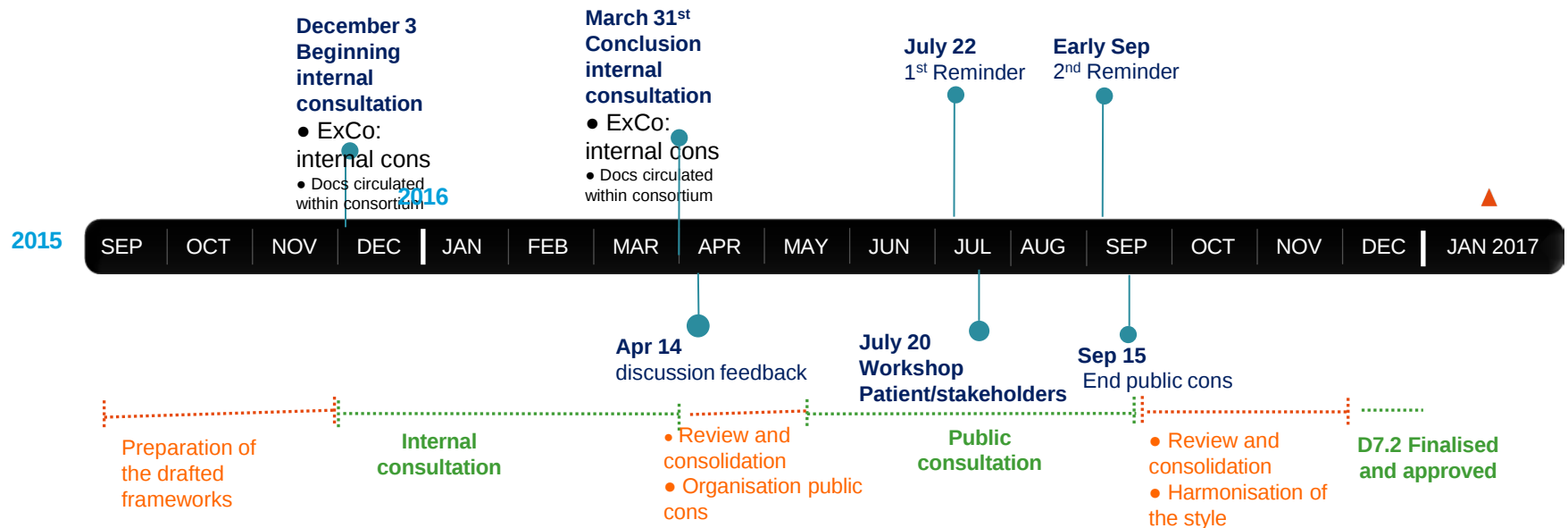
D7.2 GUIDANCES: INTERNAL & EXTERNAL PROCESS

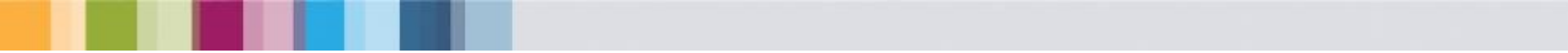
Two consultations taking place between 2015/2016

The purpose of the consultations is to gather and integrate in the drafted frameworks comments and suggestions from the EUPATI consortium and successively from external experts

- ✓ **Internal consultation (EUPATI Consortium)**
Dec 2015 - March 2016
- ✓ **Consolidation of the feedback**
March - May 2016
- ✓ **External consultation (Public for external reviewersss)**
June – Sept 2016
- ✓ **Consolidation of the feedback and finalisation D7.2**
Sept – Dec 2016

Consultation timeline D7.2





We need your feedback please

- Launch next week:
www.patientsacademy.eu/consultation
- Read letter carefully
- Word documents, with "track changes mode" enabled for download, in addition to e-mail circulation.
- Documents with suggested changes to be sent to giorgio.barbareschi@eatg.org



Keep on working hard...