EUPATI
European Patients' Academy on Therapeutic Innovation

Annual General Meeting (AGM)

18 Apr 2013, Rome/Fiumicino, Italy

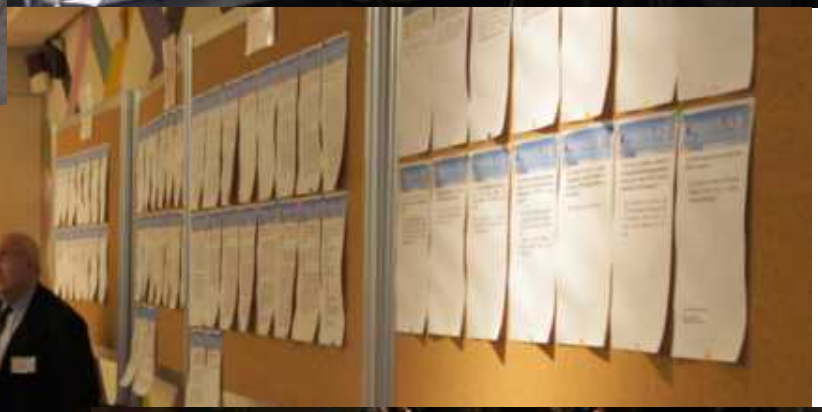
EUPATI
European Patients' Academy on Therapeutic Innovation

Progress Report

Jan Geissler

COORDINATION

EUPATI's 1st year: Much has been done! …

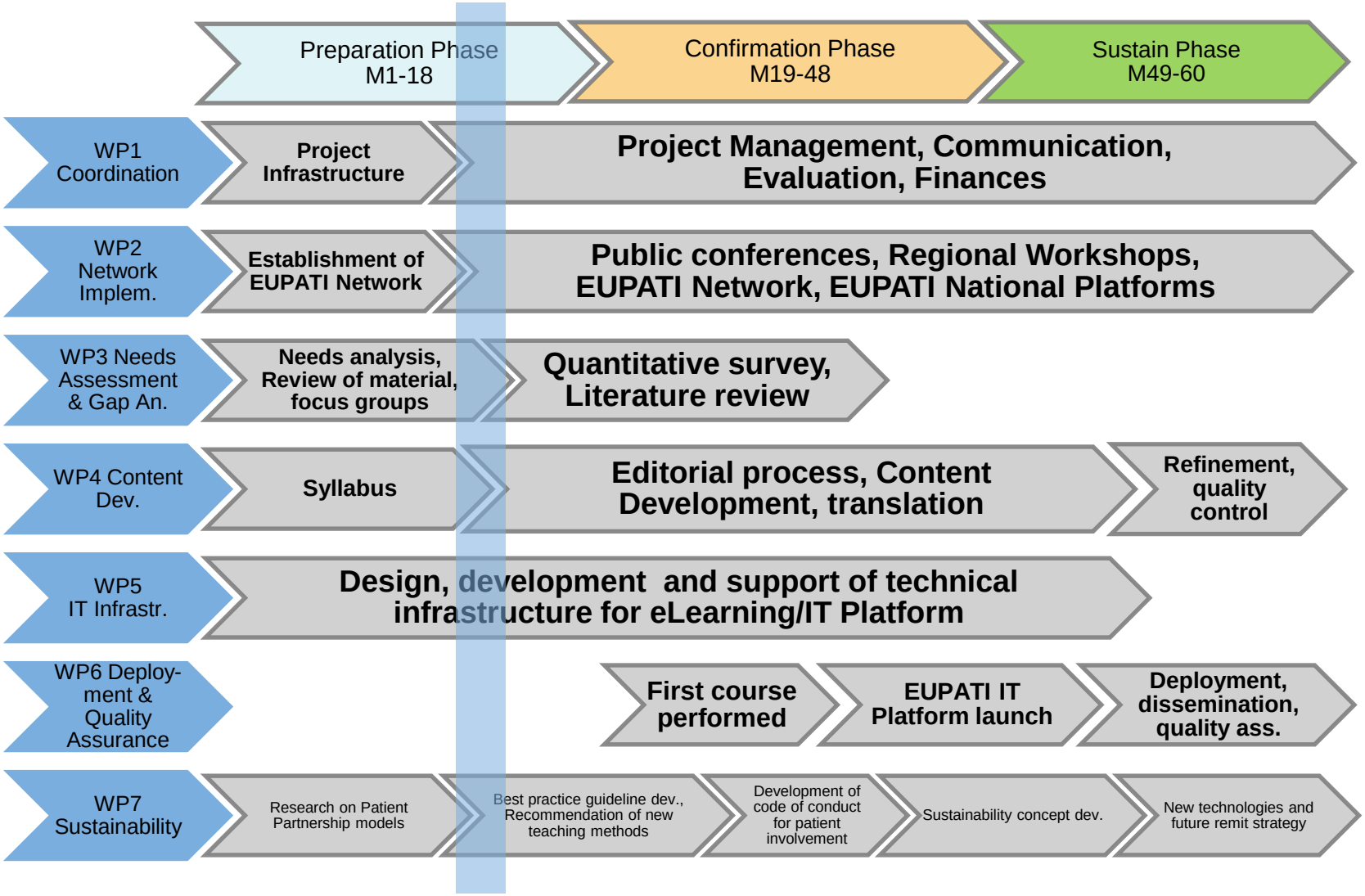


Our first year has been successful…

EUPATI
European Patients' Academy
on Therapeutic Innovation

COORDINATION

Moving from preparation phase into implementation/development phase



Website available in 7+1 languages, plus „intranets“ for consortium & advisers

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All committed deliverables have been provided to IMI

Work - Package Number	Milestone/ Deliverable	Date Due (Annex I- description of work)	Completed (Yes/Not yet/Partially)	Related document attached (Yes/No/Not applicable)
1	Governance Manual (D1.1)	M3	Yes	Yes
1	EUPATI Financial Manual (D1.2)	M1	Yes	Yes
1-7	Annual Work Plans (D1.3)	M11	Yes	Yes
1	Evaluation Plan	M3	Yes	Yes
2	Ethical Framework	M3	Partially in period 1 (completed in M12)	Yes
3	Report on review of literature and resources (D3.1)	M5	Yes	Yes
5	Functional specification defining technical platform (D5.1)	M6	Yes	Yes

Internal communications

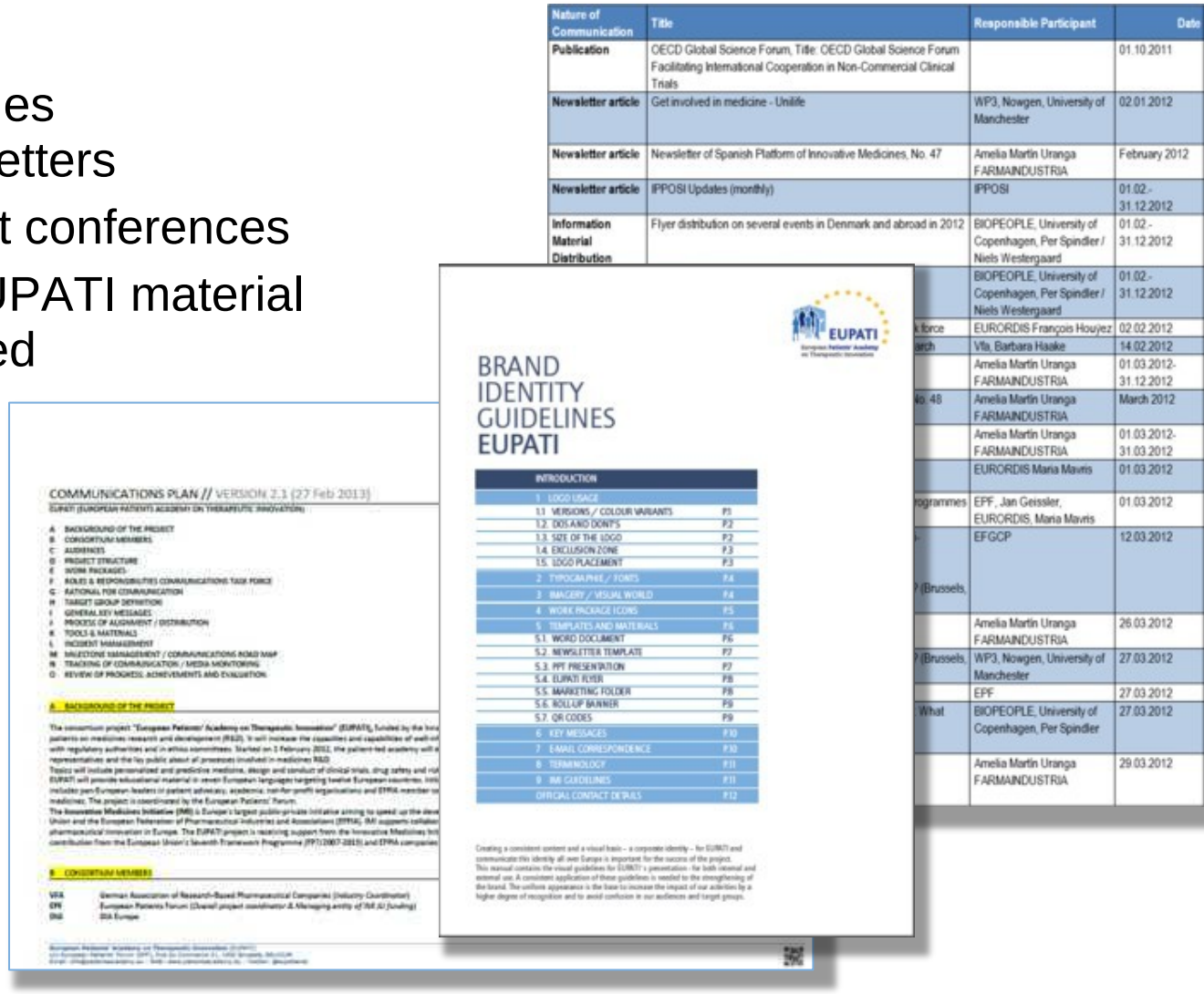
- 24 „Consortium Updates“ sent to you…

Strong public attention on EUPATI: External communications going strong

- 7 publications
- 17 newsletter articles
  + 2 EUPATI newsletters
- 49 presentations at conferences
- 8 events where EUPATI material has been distributed
- Twitter, FB, LinkedIn, G+ populated

…and:

- Communications Plan finalized
- Brand identity guide released



Nature of Communication	Title	Responsible Participant	Date
Publication	OECD Global Science Forum, Title: OECD Global Science Forum Facilitating International Cooperation in Non-Commercial Clinical Trials		01.10.2011
Newsletter article	Get involved in medicine - Unilife	WP3, Nowgen, University of Manchester	02.01.2012
Newsletter article	Newsletter of Spanish Platform of Innovative Medicines, No. 47	Amelia Martin Uranga FARMAINDUSTRIA	February 2012
Newsletter article	IPPOSI Updates (monthly)	IPPOSI	01.02.-31.12.2012
Information Material Distribution	Flyer distribution on several events in Denmark and abroad in 2012	BIOPEOPLE, University of Copenhagen, Per Spindler / Niels Westergaard	01.02.-31.12.2012
		BIOPEOPLE, University of Copenhagen, Per Spindler / Niels Westergaard	01.02.-31.12.2012
k force		EURORDIS François Houÿez	02.02.2012
arch		Vfa, Barbara Haake	14.02.2012
		Amelia Martin Uranga FARMAINDUSTRIA	01.03.2012-31.12.2012
ño. 48		Amelia Martin Uranga FARMAINDUSTRIA	March 2012
		Amelia Martin Uranga FARMAINDUSTRIA	01.03.2012-31.03.2012
		EURORDIS Maria Mavris	01.03.2012
rogrammes		EPF, Jan Geissler, EURORDIS, Maria Mavris	01.03.2012
		EFGCP	12.03.2012
(Brussels,			
		Amelia Martin Uranga FARMAINDUSTRIA	26.03.2012
(Brussels,		WP3, Nowgen, University of Manchester	27.03.2012
		EPF	27.03.2012
What		BIOPEOPLE, University of Copenhagen, Per Spindler	27.03.2012
		Amelia Martin Uranga FARMAINDUSTRIA	29.03.2012

COMMUNICATIONS PLAN // VERSION 2.1 (27 Feb 2013)

EUPATI (EUROPEAN PATIENTS ACADEMY ON THERAPEUTIC INNOVATION)

BRAND IDENTITY GUIDELINES EUPATI

INTRODUCTION

Network membership

- ~650 „EUPATI Network Members“
- ~600 Newsletter subscribers

Social Media channels started to populate about 6 weeks ago:

- 377 Twitter followers
- 292 Facebook friends

But:

Courses → **100 patient experts**

Toolbox → **12.000 patient advocates**

I‘net Library → **100.000 individuals**

Patients' Academy: up, running and real.
Workshop, 5 Sept 2012

- ~100 participants from 24 countries
- 14 countries interested to build national platforms
- Press release published in all 7 languages
- Final draft of meeting report in review, webstreams, photo gallery available

“National Platforms” Workshop,
Barcelona, 19/20 March 2013

NETWORK

“National Trios” from 10 countries present, interested to start platforms

EUPATI Ethics Panel

- „Ethical Framework“ agreed and approved
- „Declarations of Interest“ required from all individuals involved in EUPATI work
  - Ethics Panel Co-Chair reviewed 81 „Declaration of Interest“ forms
  - 25 had to be resubmitted (12 received)
  - Now published on website „About EUPATI > How we ensure objectivity, transparency, independence”
- Next steps
  - Will provide feedback on content sent to Ethics Panel for review
  - Currently reviewing TOC of Toolbox (audience 2) and Syllabus (audience 1)

Some advice received from PAB/RAP advisers

- Very positive attitude, also of “more sceptical” advisers
- Governance Manual, Code of Conduct approved
- Criticism, but also incoherent advice, on Ethics Framework (→ solved).
- Work plans are essential, request to outline our methodologies & plans:
  - **methodology and “gap analysis”** on material/literature collection (WP3),
  - on how we define **selection criteria of EUPATI course participants** (WP6),
  - **content production process**, especially quality assurance/control and editorial procedures (WP4),
  - how we keep content up to date e.g. **when regulation changes** during the course of the project, or when user feedback is provided (WP4/6),
  - on **"associate partner" engagement** of 3rd parties in EUPATI via the network, e.g. HTAi, CRUK (WP1/2/4)
  - advisors want to **review full syllabus** when ready
  - **update materials when regulation changes** during the course of the project, CTR
  - clarify **quality criteria for content** (development)
- Communication to be focused on benefits (educational gap that EUPATI is solving to empower patients) rather than processes (how we do things).

EUPATI Regulatory Advisory Panel (RAP) – more than oversight

A few results from 1st meeting on 31 Oct 2012:

- RAPs role not only to ensure objectivity, transparency and independence but also **give specific advice to teaching patients**
- **Regulatory input** (review and/or contribution to content by RAP) considered necessary when developing teaching material, e.g. for topics where regulators are thought to have particular expertise
- **Patient involvement should be regarded as a general quality criterion in medicines development and evaluation** (e.g. EPAR could regularly provide information on the kind and degree of patient involvement in the drug evaluation process)
- **Extension of the RAP:** Currently only 4 regulatory agencies. Could be expanded by regulators from further MS (e.g. France, Spain, Italy, a nordic country)
- **Generally no specific CoI is seen in EUPATI.** Transparency of *interests* would be *paramount* if EUPATI wanted to be seen as credible; RAP advised that all interests should be declared. Possible CoIs, should any exist, would then be obvious.

IQWiG‘s resignation from PAB

- In Dec 2012, IQWiG resigned from the PAB, stating that *"contrary to what was promised, the project as not taken a course"* that allows IQWiG to fulfill their advisory task as the *"package of basic documents - concerning topics such as a description of key methodological approaches and the transparent management of conflicts of interest - is not yet available in a final form.“*

IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
Institute for Quality and Efficiency in Health Care

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19. December 2012

Dear Mr. Geissler,

We regret to inform you that we are resigning from the EUPATI Project Advisory Board. In an e-mail which you sent to us on 8.10.2011, you described the project and our role within the project as follows (our translation from German).

"Under the direction of the "European Patients' Forum" (EPF), from 2012 until 2016, the project will foster collaboration between patient organisations, academic institutions, medical experts, industry, ethics committees regulatory bodies and the media. Together they will develop educational material on the topic of evidence-based medical research for the public and patients. The objective is to increase public understanding of clinical trial methods, personalised medicine, risk/benefit assessments, drug safety, health economics, health technology assessment, patient involvement in clinical research and other related topics."

"The evaluation panel and ethics committee of the IMI advised us to involve IQWiG and NICE in the Project Advisory Board, to ensure that the project is not influenced by third parties, and to benefit from IQWiG's experience in the independent assessment of evidence-based information."

Our decision to become members of the Advisory Board was based on this description of the project objectives. As an Institute, we strive to apply high standards to our core work in terms of scientific methodology and transparency. It is important to us that we maintain those same high standards in other areas of our work, including our involvement on the Advisory Board.

Unfortunately, we have come to notice that – contrary to what was promised – the project has not taken a course that allows us to fulfil the task given to us

Page 1 of 2

- DoW shared in April 2012
- Ethics Framework delayed
- Work Plans were due in M11 (Dec’12)
- Demonstrates importance to communicate our work and procedures with our advisers!

There‘s some shadow when there‘s light

- Pharma-Brief: „*Publicly funded propaganda for patients. EUPATI offers education in manufacturers‘ interest*“.

- *„A new initiative wants to educate patients on new drugs. When looking more closely, quite a lot of industry is hiding behand the European Patients‘ Academy on Therapeutic Innovation“*

- *„IMI can be seen as a ‚great coup‘ for the industry to transfer costs to the public“.*

PHARMA-BRIEF

Europa

Länder bezüglich finanzieller Verpflichtungen wesentlich zurückhaltender. Von den lateinamerikanischen Ländern unterstützte besonders Brasilien das Abkommen, brachte aber dann den schlussendlich verabschiedeten Kompromissvorschlag ein.[6]

Eine Vertreterin des Bundesministeriums für Gesundheit wertete die Entscheidung der Weltgesundheitsversammlung als guten Schritt nach vorne. Die Verhandlungen hätten gezeigt, dass noch mehr Transparenz nötig sei, welche Länder wie viel in die Forschung investieren und wo noch inhaltliche Lücken bestünden.

Der für die kommenden Monate vereinbarte Arbeitsprozess könne zielgerichtet weitere Projekte voranbringen. Verhandlungen über ein bindendes Abkommen würden eher die Gefahr bergen, in der Zwischenzeit die Umsetzung konkreter Maßnahmen zu blockieren.

Entwicklungspolitische NGOs wie Health Action International halten ein bindendes Abkommen nach wie vor für sinnvoll,' betonen aber, dass die Resolution immerhin die Chance biete, dass einige konkrete Maßnahmen umgesetzt werden. Die Hoffnung stirbt zuletzt: Bisher gibt es ein einziges völkerrechtlich bindendes Abkommen der WHO – es gilt der Tabak-Kontrolle[8] und hat ebenfalls eine schwere Geburt hinter sich. (CW)

1 Beschluss unter: http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_R22-en.pdf
2 CEWG = Consultative Expert Working Group on Research and Development: Financing and Coordination
3 Pharma-Brief (2012) Neue Forschungsmodelle haben großes Potential. Nr. 3-4, S. 1
4 WHO (2012) Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination. Geneva: WHO
5 Knowledge Ecology International KEI http://keionline.org/node/1414
6 Gulland A (2012) Plan to stimulate research in developing countries is put on hold. BMJ 344: p e3771
7 http://haiweb.org/wp-content/uploads/2012/05/144-Rev-HSI-Pharma-Policy-Brief-FD-Final.pdf
8 WHO Framework Convention on Tobacco Control www.who.int/who/tobacco/en/index.html

Propaganda für Patienten öffentlich bezuschusst

Eupati bietet Fortbildung im Herstellerinteresse

Eine neue Initiative will PatientInnen über neue Arzneimittel aufklären. Hinter der „Europäischen Patientenakademie zu Therapeutischen Innovationen" (Eupati) verbirgt sich bei näherem Hinsehen aber ziemlich viel Industrie.

Auch wenn auf den ersten Blick die Pharmaindustrie bei Eupati

borgen bleibt."[2] Ganz so als würde die Industrie nicht mantraartig

auch benannt: „Mit einem geeigneten Training können Patientenvertreter akzeptierte Partner in Wissenschaft, Ethik- und Kontrollausschüssen werden, und dabei klinische Studien, Arzneimittelentwicklung und Zugangsstrategien

Focus groups:
7 pan-European & 1 UK completed

- To provide a detailed and in depth understanding of the attitudes and information needs of various stakeholder groups to medicines development.
- The stakeholders are patients, the general public, pharma representatives, and health professionals

Focus groups to be conducted:

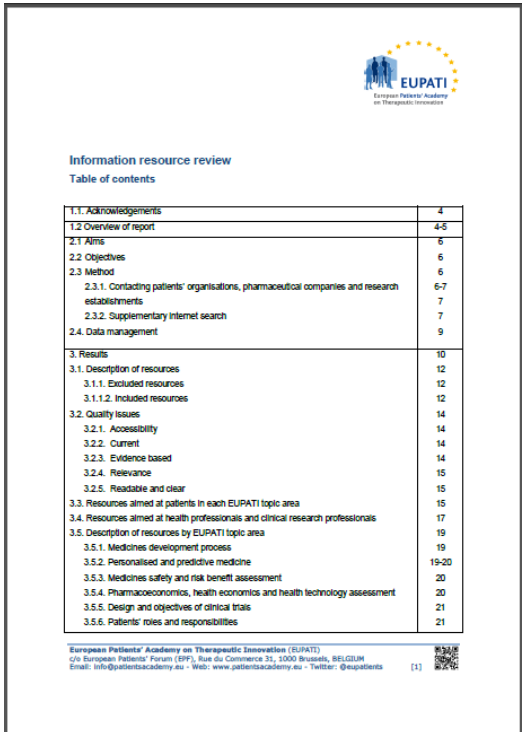
- In England, Spain & Poland:
  - 3 x FGs – Patients, patient advocates
  - 2 x FGs – Members of the public
  - 1 x FG – Health professionals, policy makers and advisors
  - 1 x FG – Pharmaceutical professionals
- + Pan-European FGs associated with EUPATI events

Results:

- Valuable feedback on patient advocates' beliefs, information needs and information format, interim report about to become available

Review of Educational Material

- ‘Snapshot’ of existing resources published on website
  - 306 submissions via EUPATI website from various stakeholders
  - Categorisation: scientific topic area, audience, format, language, etc
  - Recommendations for EUPATI content dev. discussed with WP4
  - Presented at DIA EuroMeeting, Regional Workshops



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European Patients' Academy on Therapeutic Innovation

Information resource review

Table of contents

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EUPATI Work Package 3 - List of Resources suggested to EUPATI

EUPATI
European Patients' Academy on Therapeutic Innovation

List of Resources suggested to EUPATI

Author	Title	Abstract	Date	Language	Main target group
DHF2	A brief overview: how clinical trials take place		Unknown	German	Patients at large - lay patients and the general public
European society for medical oncology	A guide for patients with advanced cancer: Getting the most out of your oncologist		2011	English	Cancer patients
Novo Nordisk	A Responsible approach to clinical trials	This brochure provides an introduction to clinical trials and outlines global ethical standards as well as Novo Nordisk's position regarding clinical trials. It further explores sponsoring a clinical trial, conducting and participating in a clinical trial.	Post 2008	English	Patients at large - lay patients and the general public
	A Way Forward?	Report from the European Forum for Good Clinical Practice drafted by the Research Integrity Subgroup of the European Forum of Good Clinical Practice Ethics Working Party.	June 2010	English	Clinical Research Professionals
Association of the British Pharmaceutical Industry (ABPI)	ABPI interactive resources for schools.	This Association of the British Pharmaceutical Industry (ABPI) Resources for Schools website provides curriculum related resources for use by teachers and their pupils. The resources have been developed by the ABPI and many link to topics studied in school.	Unknown	English	Young people aged 5 - 18, and their teachers.
vfa	Achtung viral	Short cartoon film about immunisation.	2010	German	Patients at large - lay patients and the general public
PHG Foundation	All educational material from PHG Foundation	Educational material relating to genetics, population genomics etc. A login is required.	3-5 years ago	English	Patients at large - lay patients and the general public
UK Clinical Research Collaboration	An evaluation of the process and impact of patient and public involvement in the advisory groups of the UK Clinical Research Collaboration	Training course.	Jan 2009	English	Clinical Research Professionals
Amgen	An introduction to Biotechnology	Describes the development of biotechnology medicines from the underlying science to clinical development, approval and manufacturing and gives examples for types of biotechnology medicines.	2009	English	Patients at large - lay patients and the general public
London School of Economics	An introduction to financing health care in Europe	Health Economics, Health Policy and the Economics of HIV/AIDS, A course for Representatives of HIV Advocacy Organizations, LSE Health - The London School of Economics and Political Science.	March 2007	English	Expert level patients
GSK	Animals in medical research - A pharmaceutical company point of view.	This Powerpoint presentation covers the following questions: Why are animals used? Why aren't alternatives to animals used? What animals are involved? What happens to the animals? Who benefits from animal research?	Unknown	English	Patients at large - lay patients and the general public
Amgen, NN	Antibody Therapeutics: Biology and Clinical Application	Describes background and characteristics of monoclonal antibodies as targeted therapies.	Unknown	English	Clinical Research Professionals?
Cheryl Savins, Judy Mahak, Diane Paul, Alexy Xie	Are You Thinking About Being in a Research Study?	The US Human Research Protection Education Program. Since 2010 investigators and associated staff participating in the NIH grant system and the VA, as well as individuals willing to participate as institutional Review Board members, are required to take specific short training.	Unknown	English	Patients at large - lay patients and the general public
vfa	A1 Patient in clinical trials; Children and adolescents in clinical trials; Research for live; for children WAS IST WAS: Wie erstellt ein Medikament?, and some more titles	Brochures for the lay audience	2011	German	Patients at large - lay patients and the general public
AstraZeneca	A2 drug development process	A2 drug development process	Unknown	English	Patients at large - lay patients and the general public
Vienna School of Clinical Research	Basic Good Clinical Practice (eCourse)		Unknown	English	Clinical Research Professionals
CISCRP	Become educated about clinical trials	Webpage.	Unknown	English	Patients at large - lay patients and the general public
Wellcome Trust	Big Picture on Drug Development	Big Picture - Brings cutting-edge science into the classroom. Published twice a year, 'Big Picture' is a free resource for teachers that explores issues around biology and medicine.	Jan 2008	English	Students and teachers
Novo Nordisk	Bioethics and the use of animals in research	This brochure outlines Novo Nordisk's approach to bioethics and the use of animals in research and development including global standards and its principles on the use of animals.	7.5-24 mths ago	English	Patients at large - lay patients and the general public
Novo Nordisk	Bioethics at Novo Nordisk	The Bioethics page covers Bioethics at Novo Nordisk, a systematic approach to bioethics, dialogue and collaboration and e-learning tools on ethics. The tools are listed separately in this review.	2012	English	Patients at large - lay patients and the general public
Eli Lilly Pharma	Biosimilars; Growing the concepts	Describes how to assess biosimilars from a regulatory perspective.	Oct 2008	English	Clinical Research Professionals
interpharma	Biotech Learning Centre	interpharma is the association of research-based pharmaceutical companies in Switzerland. Students and teachers will find information and examples from the field of modern biological and medical research.	Unknown	German	Patients at large - lay patients and the general public

Recommendations from the resource review

- **Medicines development process:** adapt existing overviews, tackle specific areas in more detail;
- **Personalised and predictive medicine:** few resources; difficult area for patients to interpret.
- **Medicines safety and risk-benefit assessment:** adapt Pharmacovigilance resources aimed at health professionals
- **HTA:** few resources for patients; more needed.
- **Design & objectives of clinical trials:** focus on specific aspects eg. how research priorities are established;
- **Patient roles & responsibilities:** scope for a range of resources

Resource review – list made available on the EUPATI website

	Medicines development process from research to approval	Personalised and predictive medicine	Drug safety and risk benefit assessment of novel or existing medicines	Pharmacoeconomics, health economics or health technology assessment	Design and objectives of clinical trials	Patients roles and responsibilities	Other
Patient advocates	5	0	3	5	5	6	1
Expert patients	1	1	1	16	1	1	3
Patients at large	74	21	77	13	65	42	6
Total	**80**	**22**	**81**	**34**	**71**	**49**	**10**

EUPATI Syllabus for audience 1

Example: EUPATI Face2Face Training Courses

1. **Discovery of Medicines & Planning of Medicines Development**
2. **Non-Clinical Testing and Pharmaceutical Development**
3. **Exploratory and Confirmatory Clinical Development**
4. **Clinical Trials**
5. **Regulatory Affairs, Medicinal product Safety, Pharmacovigilance and Pharmaco-epidemiology**
6. **Health Technology Assessment and the economics of healthcare**

EUPATI Syllabus for audience 1

Example: EUPATI Face2Face Training Courses

1. **Discovery of Medicines & Planning of Medicines Development (→ 19 sub-topics)**
2. **Non-Clinical Testing and Pharmaceutical Development (→ 8 sub-topics)**
3. **Exploratory and Confirmatory Clinical Development (→ 14 sub-topics)**
4. **Clinical Trials (→ 37 sub-topics)**
5. **Regulatory Affairs, Medicinal product Safety, Pharmacovigilance and Pharmaco-epidemiology (→ 27 sub-topics)**
6. **Health Technology Assessment and the economics of healthcare (→ 28 sub-topics)**

= 133 sub-topics to be taught in the face2face courses!

eLearning Platform

- Draft technical specification of WP5's e-Learning platform has been delivered.

- (placeholder, to be added) WP5 – need input from WP6 leaders

Some challenges in EUPATI

- **Challenges to convene volunteer advisory boards** in due time (e.g. Ethics Panel)
- **Time required for constructive consultations** with advisors, e.g. agreement on management of potential conflicts of interest
- **Delay of recruitment of project staff** at some public institutions (short time between signature of GA and project start)
- Finalisation of the evaluation plan required the **existence of WP Work Plans** (M11)
- **First findings on teaching methodology** and choice of media required before functional specification of a technical platform can be drafted.
- **Managing enthusiasm in NLTs** before framework was clearly defined
- **Some partners were very involved, some less…**

Get to know us!

EUPATI
European Patients Academy on Therapeutic Innovation

Web:
www.patientsacademy.eu

Twitter: @eupatients
as well as: