

EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK - TRANSNATIONAL WORKING GROUPS

ECRIN-TWG



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Deliverable 24 **Survey on existing education programmes within the ECRIN member states**

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Summary

Clinical research is the basis of a well functioning, evidence-based health care system. In 2004, the European Directive 2001/20/EC aimed to promote harmonisation within European clinical research.

The comparative analysis on clinical research education presented in the ECRIN-RKP project showed a major diversity in national education programmes for investigators, study nurses and all the staff involved in clinical research. The definition of clinical research jobs and related tasks differed from one country to another.

The task of European Clinical Research Infrastructures Network (ECRIN) Working Party 8 is to describe the existing education programmes on clinical research within the ECRIN member states through a repository.

This was achieved through the development of an online web survey on course packages. The objective was to focus on the infrastructural level in each ECRIN member state.

Most ECRIN member states provide one or many international courses, and more than 50% of the course providers in most countries have accredited courses.

The web survey data provides a brief overview of the current course packages within ECRIN. As the web survey was open during a limited period, information on course providers are missing from most countries. This information will be entered into a continuously open repository in the next ECRIN step (PPI).

A future aim of ECRIN WP on education and training will be to develop the web survey into a more detailed repository for further investigation on course packages as well as specific courses. This could help ECRIN develop course standards and course certifications.

A Background

European Clinical Research Infrastructures Network (ECRIN) is designed to bridge the clinical research in Europe through the interconnection of national networks of clinical research centres (CRC) and clinical trial units (CTU) and to develop services to provide support for multicentre clinical studies in Europe.

Personnel working with clinical trials have different backgrounds and there are special requirements on skills and experience, according to ICH-GCP, for certain professions, and other requirements for others.

At hospitals and in phase-1 units usually physicians and nurses are responsible for direct actions. By regulations, the investigator must be a physician with experience from previous clinical trials and specialist in the area of concern. The other personnel in the clinical trial team should be skilled and works on delegation from the investigator. Other people involved in clinical trials (project managers, data managers, statisticians and others) must perform their work according to the standards given by the ICH-GCP, although their qualifications are not formally expressed in the ICH-GCP.

In the first ECRIN FP6-funded project (ECRIN-RKP, 2004-2005) a survey was made within the ECRIN member states, to perform a comparative analysis of clinical research education and training.

The comparative analysis presented in the ECRIN-RKP project showed a major diversity in national education programmes for investigators, study nurses and all the personnel involved in clinical research. The definition of clinical research professions and related tasks also differed from one country to another. There was a major diversity between the reporting countries in length of the courses, the topics, the target groups and the course providers.

The education and training of clinical trial personnel is a prerequisite for conducting clinical research according to national and international regulations. The task of European Clinical Research Infrastructures Network (ECRIN) Working Party 8 is to describe the existing education programmes on clinical research within the ECRIN member states in a repository.

B Methodology

To build a broad scope repository on existing educational learning status within ECRIN, WP8 designed a questionnaire for national course packages. No detailed questions were used as the focus was on the infrastructural level in each ECRIN member state.

A draft version of the survey was designed by the chair and a few members of Working Party 8 and discussed during teleconferences until agreement of the final version which was transformed into the online survey program Texttalk.se Websurvey.

The survey contains 11 mandatory sections:

- ECRIN member state
- Name of institution providing courses for clinical research
- Number of courses provided
- Language of the course
- Course arena
- Information about course provider
- Information on the course package
- Type of courses
- Information about course participants
- End of courses
- Accreditation of courses

According to the design of the survey, one course provider should fill in one questionnaire. An unlimited number of web surveys could then be filled in by each ECRIN member state.

The online survey was open from April 1st until May 2nd 2008, to be filled in either by national institutions and course providers or by national representatives of WP8 or European Correspondents.

Finland entered as a new partner in the working party 8 after the closure of the survey. Information from Finland was collected separately with a prolonged opening of the web survey until the 5th of June.

C Results of the survey

A summary of all the answers from the responding ECRIN member states are presented in a table below, as well as separate results from each member state.

The data collected in this web survey does only give a brief view on the course packages within the ECRIN member states. A few countries have only provided information from one single course provider and most of the countries have information on other course providers or courses to add in future web surveys.

The following ECRIN member states are represented: Austria, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Spain, Sweden, Switzerland and United Kingdom.

Summary of all responding countries

ECRIN member state:	AT	DK	FI	FR	DE	HU	IE	IT	ES	SE	CH	UK
Course provider												
University/University affiliated												
For profit organisation												
Course area												
Courses in english exist												
International courses exist												
National courses												
Course content												
General GCP/GSP courses												
Regulatory requirements												
Data Management												
SOP												
Biostatistics												
Ethics												
(Pharmaco)vigilance												
Monitoring												
Protocol development												
Trial site management												
Others												
Type of courses												
ECTS points												
Face-to-face courses												
E-learning courses												
Course participant												
Physician/Investigator												
Biostatistician												
Study nurse												
Monitor/CRA												
Member of ethics committee												
Others												
End of courses												
Examination												
Diploma												
Certificate												
Other												
Accredited courses	A	B	B	A	A	▫	A	A	B	A	A	A▫

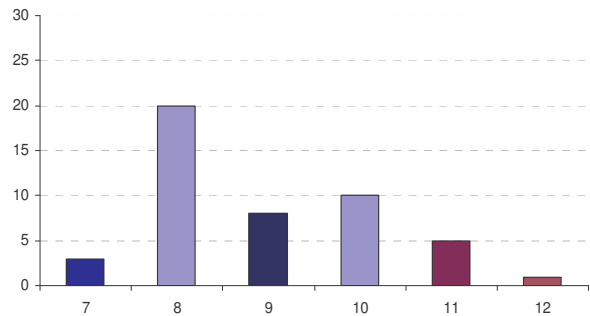
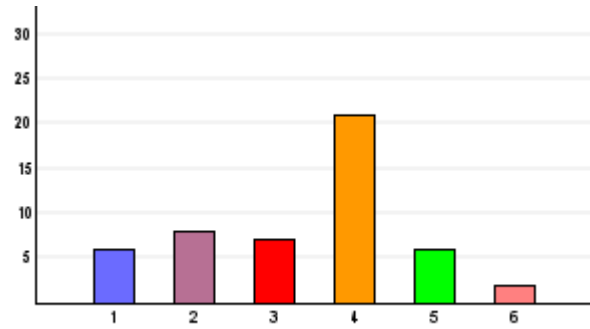
Abbreviations: **A**= More than 50% of course providers have accredited courses. **B**=Less than 50% of course providers have accredited courses. **▫**=Represents only one course provider.

White box = The criteria is not fulfilled by the course provider information collected in April/May 2008.

ECRIN member state

Total number of responses: 97

(1) Austria	6
(2) Denmark	8
(3) Finland	7
(4) France	21
(5) Germany	6
(6) Hungary	2
(7) Ireland	3
(8) Italy	20
(9) Spain	8
(10) Sweden	10
(11) Switzerland	5
(12) United Kingdom	1

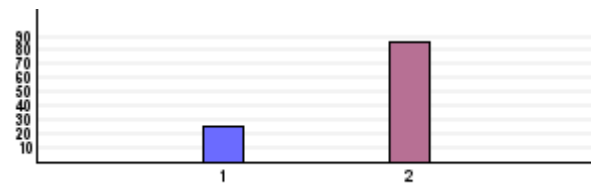


Language of the courses

Total number of responses: 97

(1) English	25
(2) Other, please specify	85

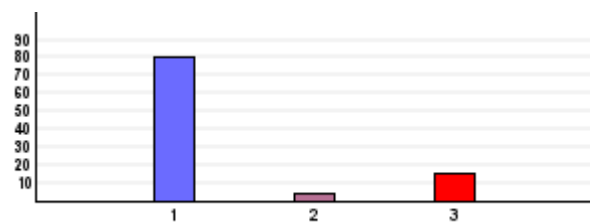
Other, please specify: French, German, Italian, Spanish, Swedish, Danish, Finnish



Course arena:

Total number of responses: 97

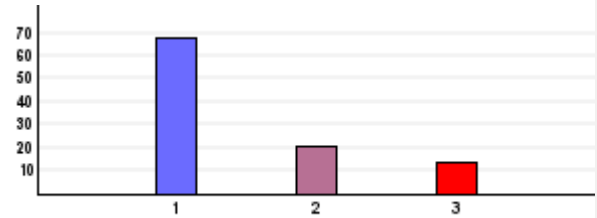
(1) National	79
(2) International	4
(3) Both national and international	15



Information about course provider:

Total number of responses: **97**

■ (1) University or university affiliated	67
■ (2) For-profit organization	21
■ (3) Other, please specify	14



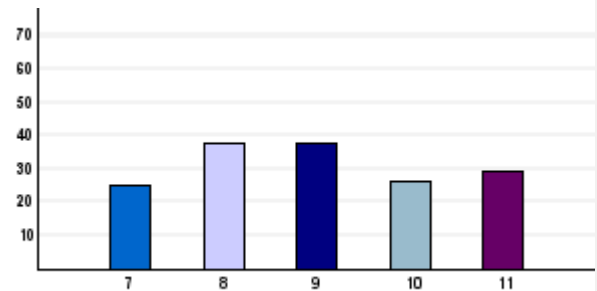
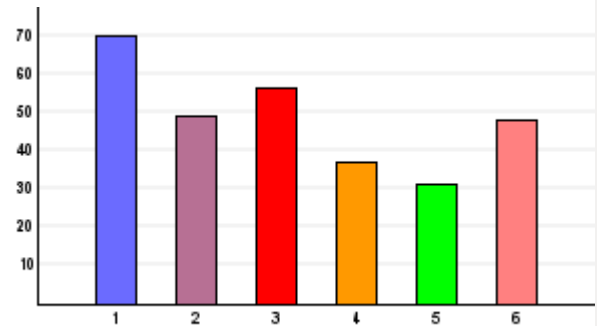
Other, please specify:

Cluster organisation, College of Medical Doctors (Barcelona), Governmental Agency no-profit, local health government school, Not-for-profit university affiliated association, non-profit organization, Pharmaceutical Industry, Research institute, Some courses are organized jointly with other non-profit organizations.

Information on the course package:

Total number of responses: **97**

■ (1) General GCP/GSP courses	70
■ (2) Ethic principles of clinical research	49
■ (3) Regulatory requirements for clinical research	55
■ (4) (Pharmaco) vigilance	37
■ (5) Data management	31
■ (6) Monitoring	47
■ (7) SOP	25
■ (8) Protocol development	38
■ (9) Biostatistics	38
■ (10) Trial site management	26
■ (11) Others, please specify	29



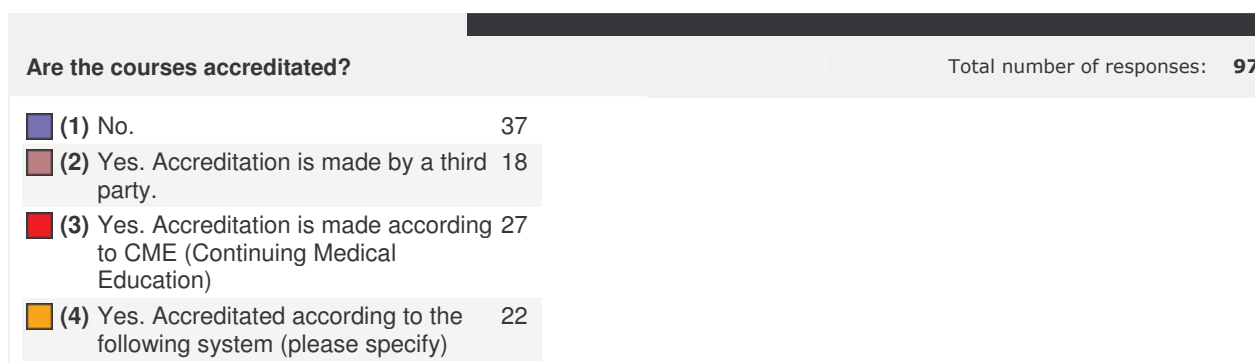
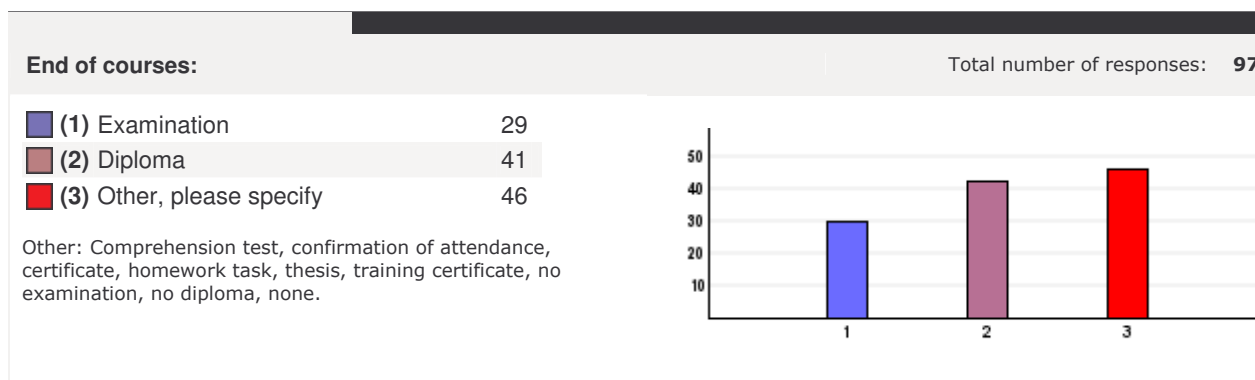
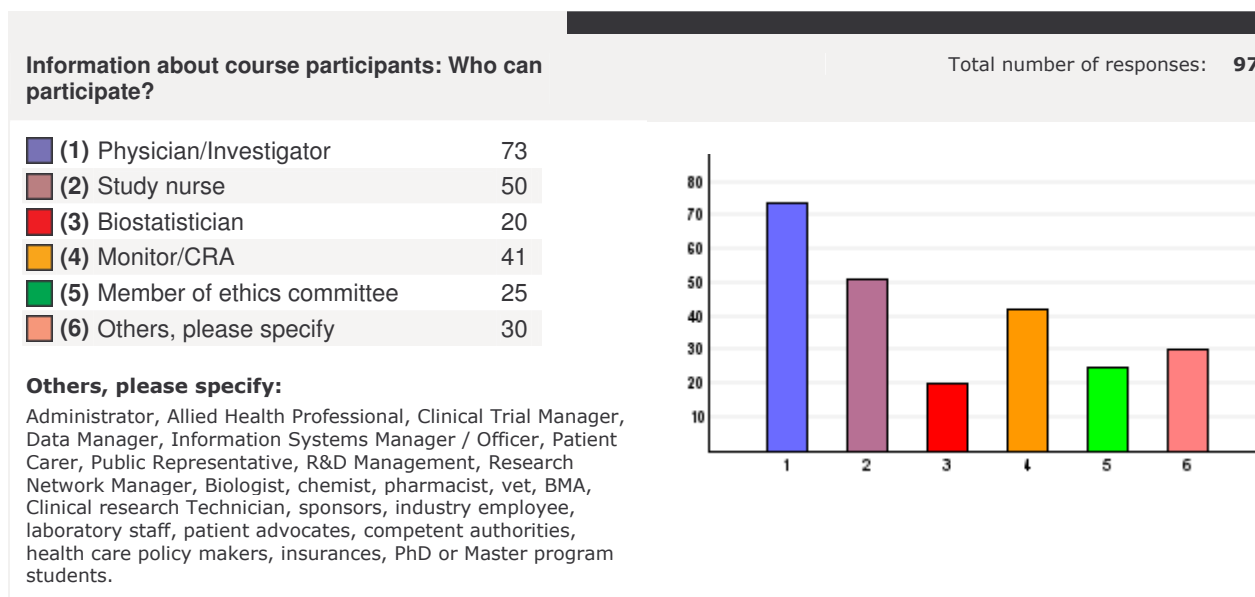
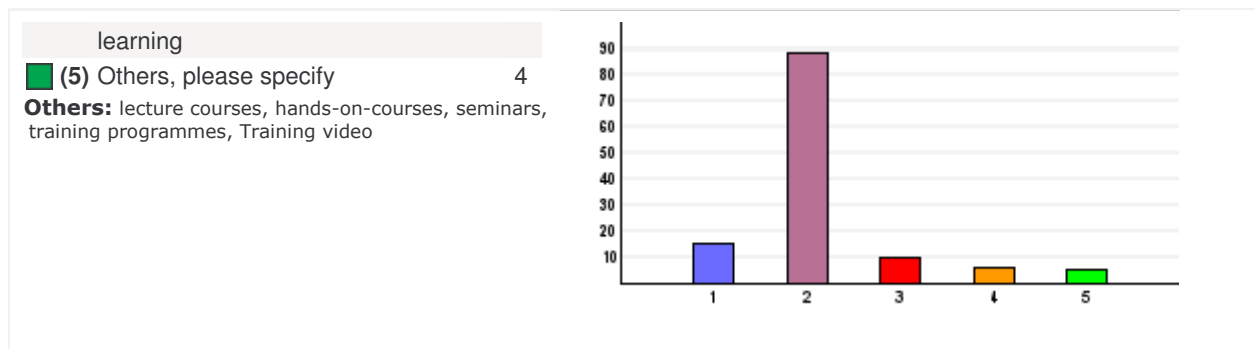
Others: Please Specify:

Specific aspects of biotherapy and genetic studies, management of biological samples, clinic and epidemiologic evaluation of drugs/ review of clinic pharmacology results, GCLP, Grant applications, Patient advocacy, evidence-based medicine, drug policy making, pharmaco-economics, publication, patient information and informed consent, health technology assessments, Contracting in clinical trials, communication skills, Clinical Pharmacokinetics, Pharmacogenetics, patents, EBM, systematic review, European Diploma/Masters in Pharmaceutical Medicines, MHRA Inspection & Audit, Patient and Public Involvement, Working with Industry, Disease specific courses, MBA (Pharma Industry), Report writing, Medical Device, Project management, Training leading to a qualification of Clinical Research Assistant.

Type of courses:

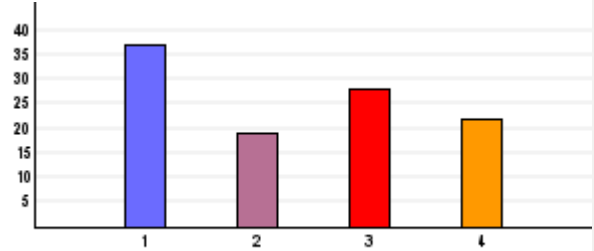
Total number of responses: **97**

■ (1) ETCS points	15
■ (2) Face to face courses	87
■ (3) E-learning courses	10
■ (4) Combination of face to face and e-	6



Yes. Accredited according to the following system (please specify):

60 ETC credits, by the Faculty of Health Sciences PhD committee, Diploma by the three EUCOR medical schools, KKS Network (Germany), Medical faculties, Swiss Association of Pharmaceutical Medicine, The courses are part of post-graduate programmes of the Medical University of Vienna, University Accreditation, University of Kuopio complies with the requirements of the standard SFS-EN ISO 9001:2000



Austria

Name of institution providing courses for clinical research and number of courses provided:

Total number of responses: **97**
Selected responses: **5**

Österr. ARGE f. Klin. Pharm. u. Therapie	2 per year
Human.technology Styria GmbH	4
Medical University of Graz	1
Medical University Innsbruck	5
Vienna School of Clinical Research	around 35 courses per year

Filter

Selection

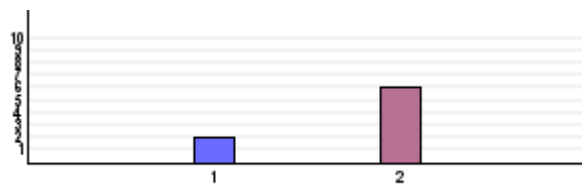
ECRIN member state

Austria

Language of the courses

Total number of responses: **97**
Selected responses: **5**

(1) English	1
(2) Other, please specify	5
Other: French, german	



Filter

Selection

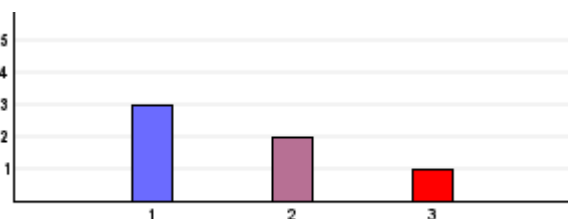
ECRIN member state

Austria

Course arena:

Total number of responses: **97**
Selected responses: **5**

(1) National	3
(2) International	2
(3) Both national and international	1



Filter

Selection

ECRIN member state

Austria

Information about course provider:

Total number of responses: **97**
Selected responses: **5**

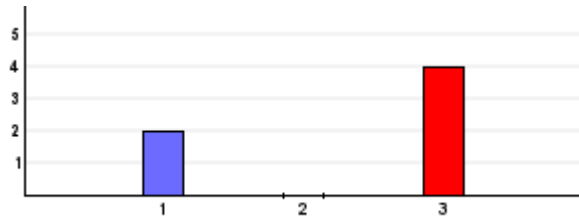
- (1) University or university affiliated 2
- (2) For-profit organization 0
- (3) Other, please specify 4

Other, please specify:

Cluster organisation

 Not-for-profit university affiliated association

 non-profit organization



Filter	Selection
ECRIN member state	Austria

Information on the course package:

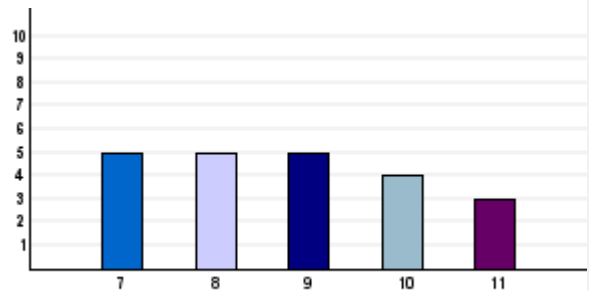
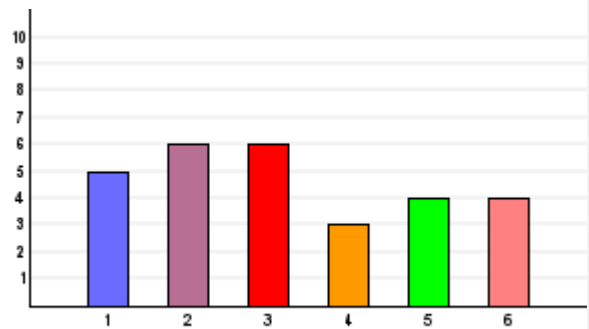
Total number of responses:: **97**
Selected responses:: **5**

- (1) General GCP/GSP courses 5
- (2) Ethic principles of clinical research 6
- (3) Regulatory requirements for clinical research 6
- (4) (Pharmaco) vigilance 3
- (5) Data management 4
- (6) Monitoring 4
- (7) SOP 5
- (8) Protocol development 5
- (9) Biostatistics 5
- (10) Trial site management 4
- (11) Others, please specify 3

Others, please specify:

Clinical Epidemiology, GCLP, Grant applications, Patient advocacy, evidence-based medicine, drug policy making, pharmaco-economics, publication, patient information and informed consent, health technology assessments

 the course provides an introduction into all these topics related to clinical research

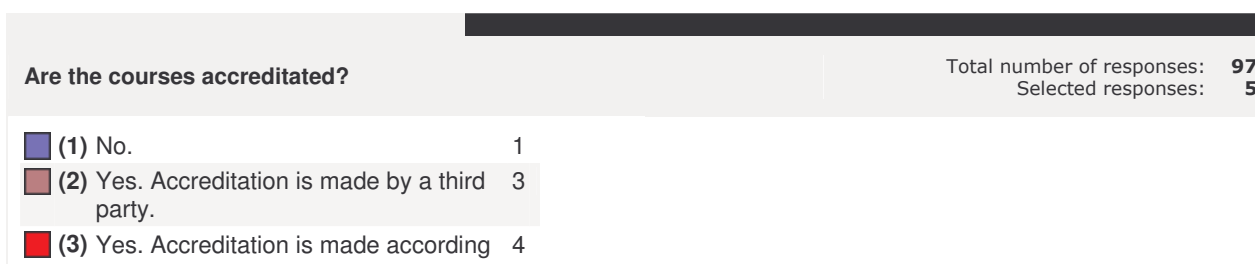
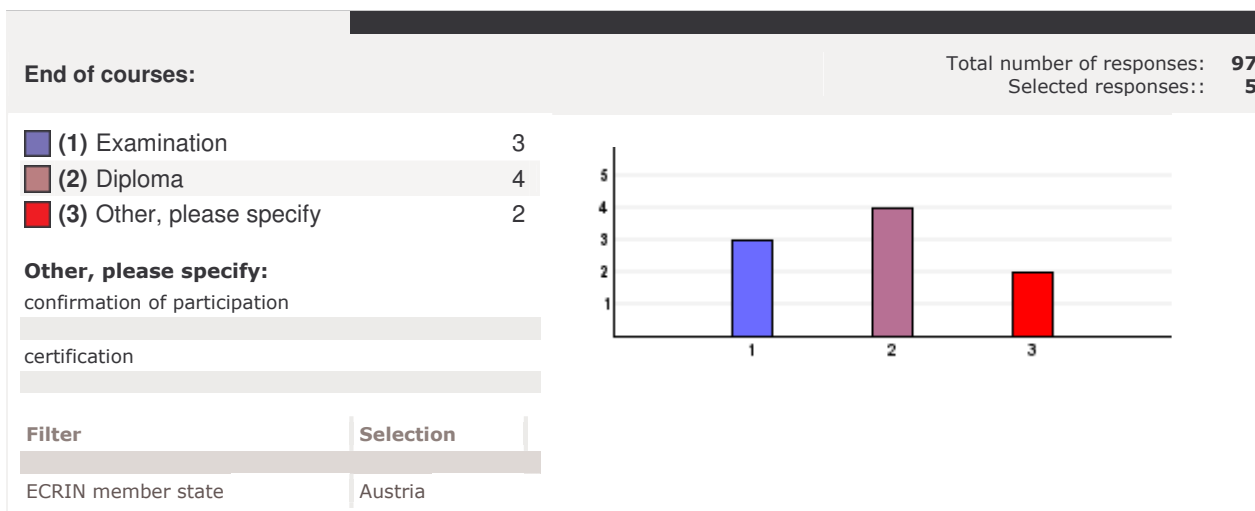
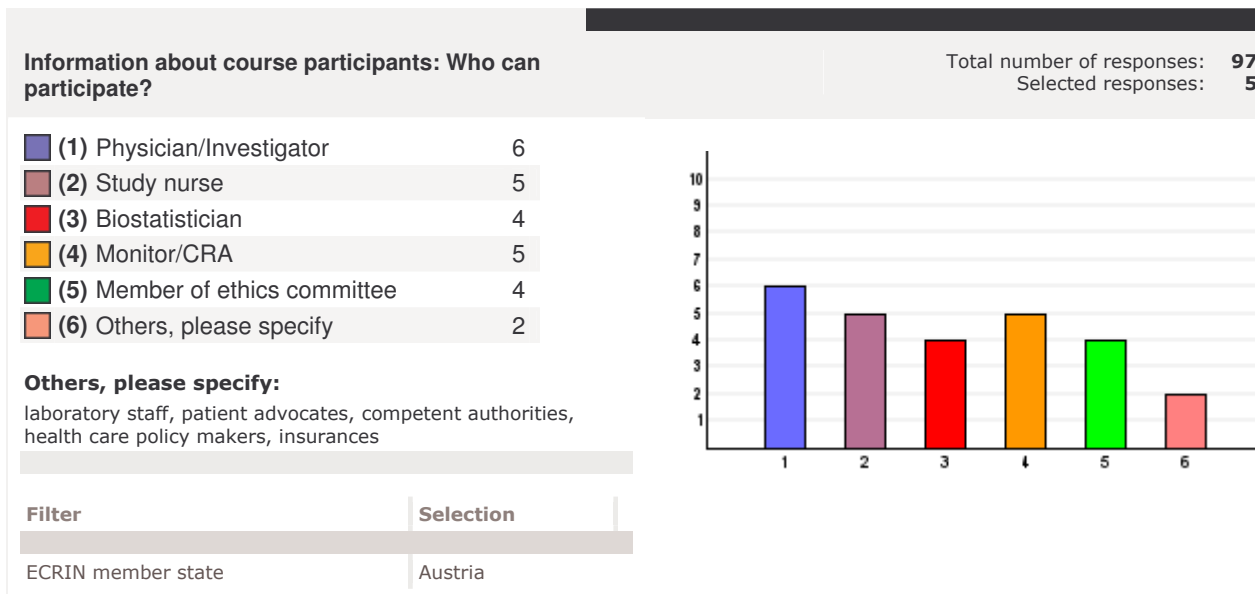
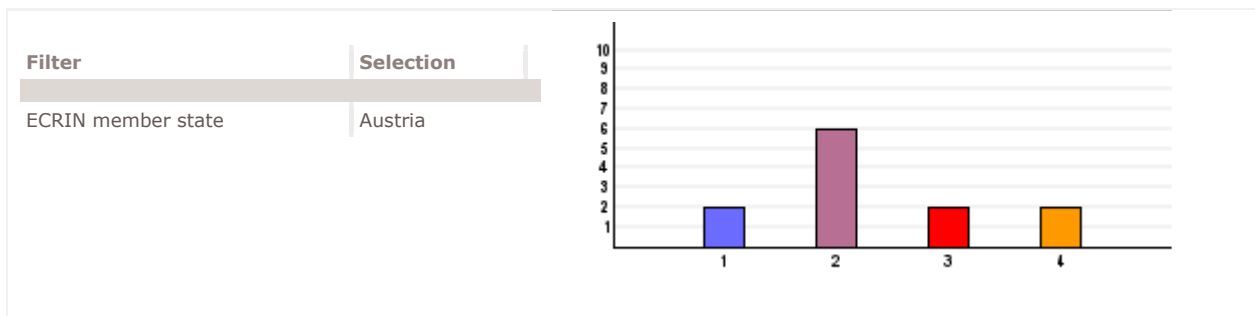


Filter	Selection
ECRIN member state	Austria

Type of courses:

Total number of responses: **97**
Selected responses: **5**

- (1) ETCS points 2
- (2) Face to face courses 6
- (3) E-learning courses 2
- (4) Combination of face to face and e-learning 2

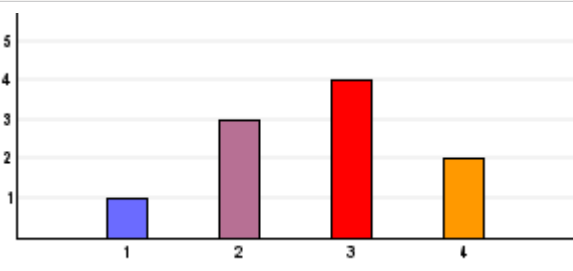


to CME (Continuing Medical Education)

(4) Yes. Accredited according to the following system (please specify) 2

Yes. Accredited according to the following system (please specify):
 The courses are part of post-graduate programmes of the Medical University of Vienna

Filter	Selection
ECRIN member state	Austria



Level	Count
1	1
2	3
3	4
4	2

Denmark

Name of institution providing courses for clinical research and number of courses provided:

Total number of responses: 97
Selected responses: 8

Copenhagen University	9
Odense University Hospital, The GCP-unit	One in 2007
GCP-Unit, Copenhagen University Hospital	3
University of Southern Denmark	3
The GCP-unit, Aarhus University Hospital	3
Pharmacon	3
Association of the Pharmaceutical Ind.	4
University of Aarhus	4

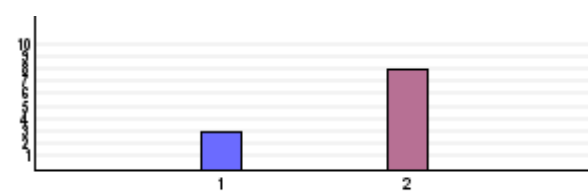
Filter	Urval
ECRIN member state	Denmark

Language of the courses

Total number of responses:: 97
Selected responses:: 8

(1) English 3
 (2) Other, please specify 8
 Other: Danish

Filter	Selection
ECRIN member state	Denmark



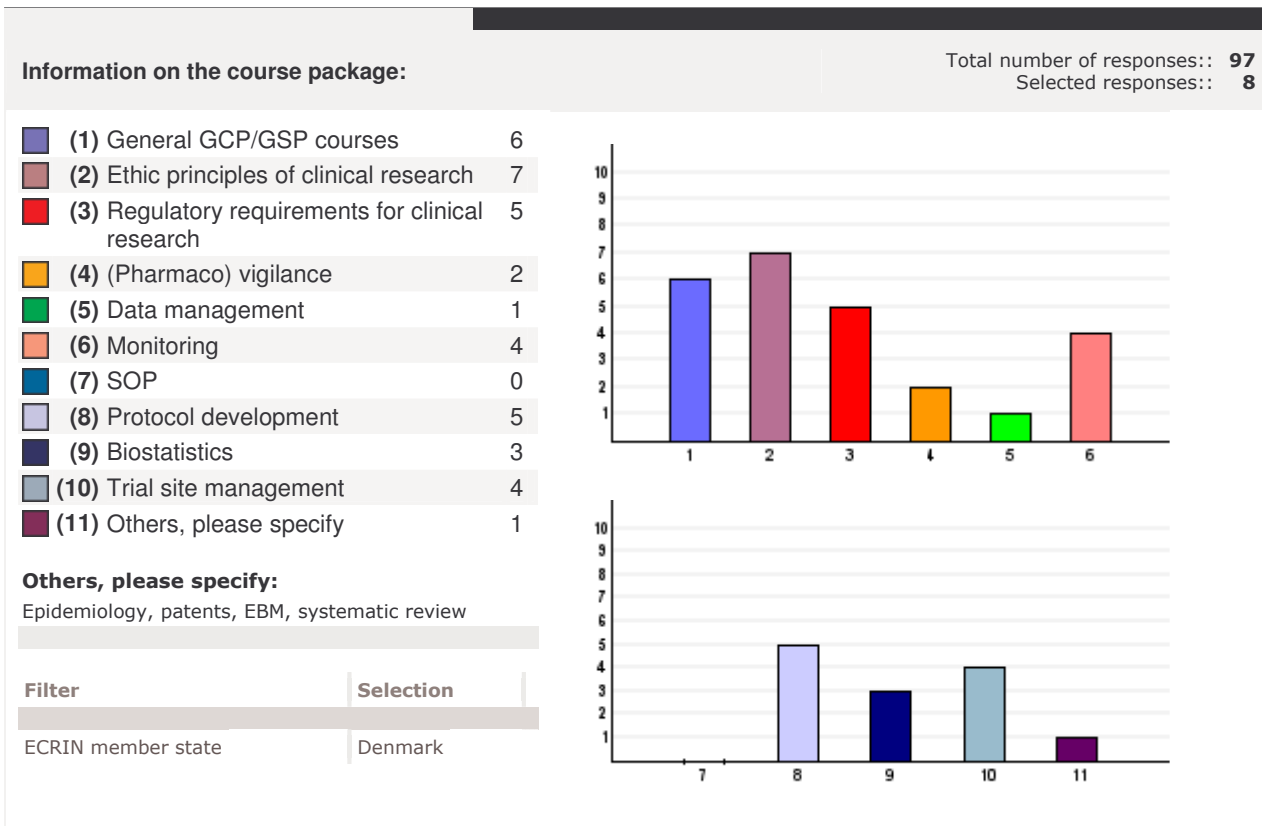
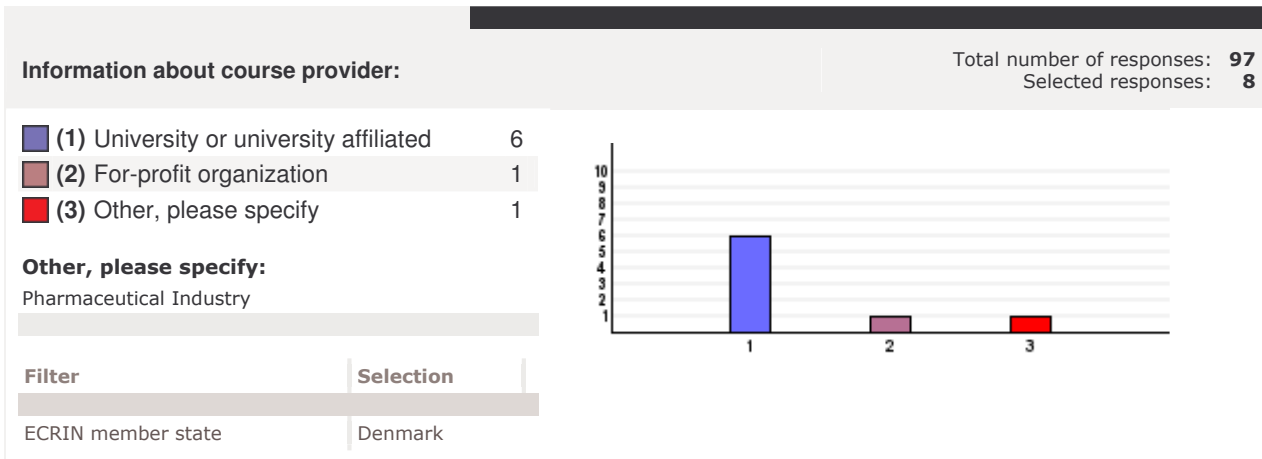
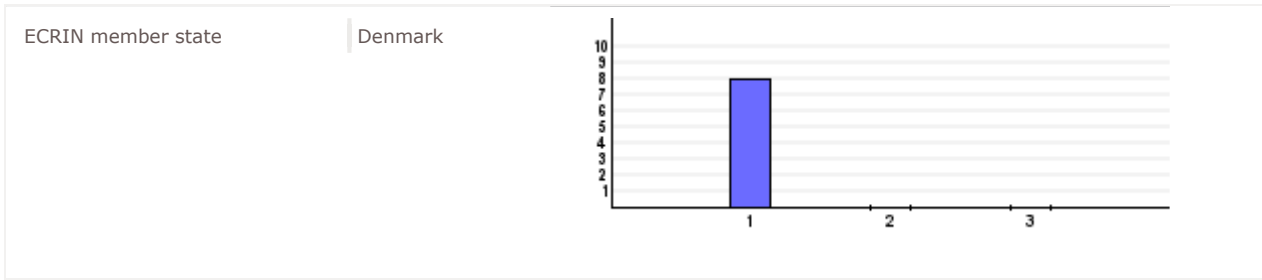
Category	Count
1	3
2	8

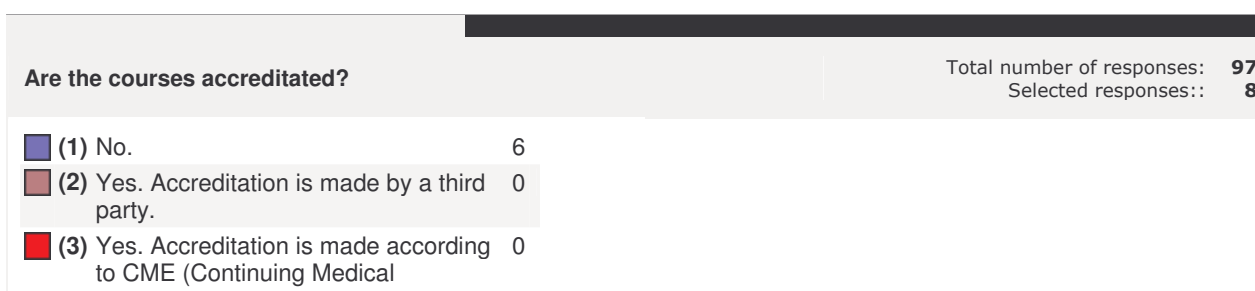
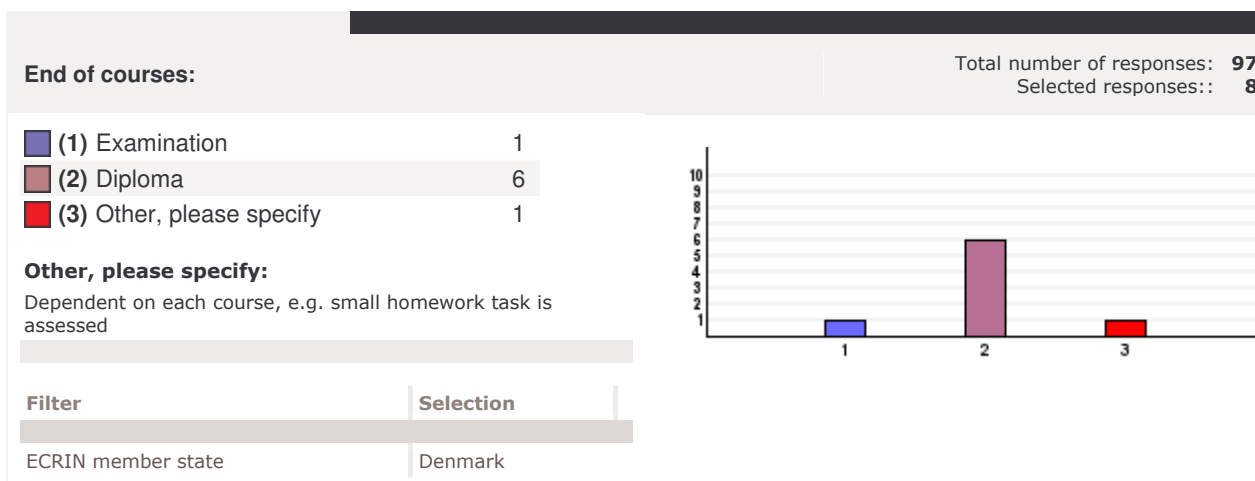
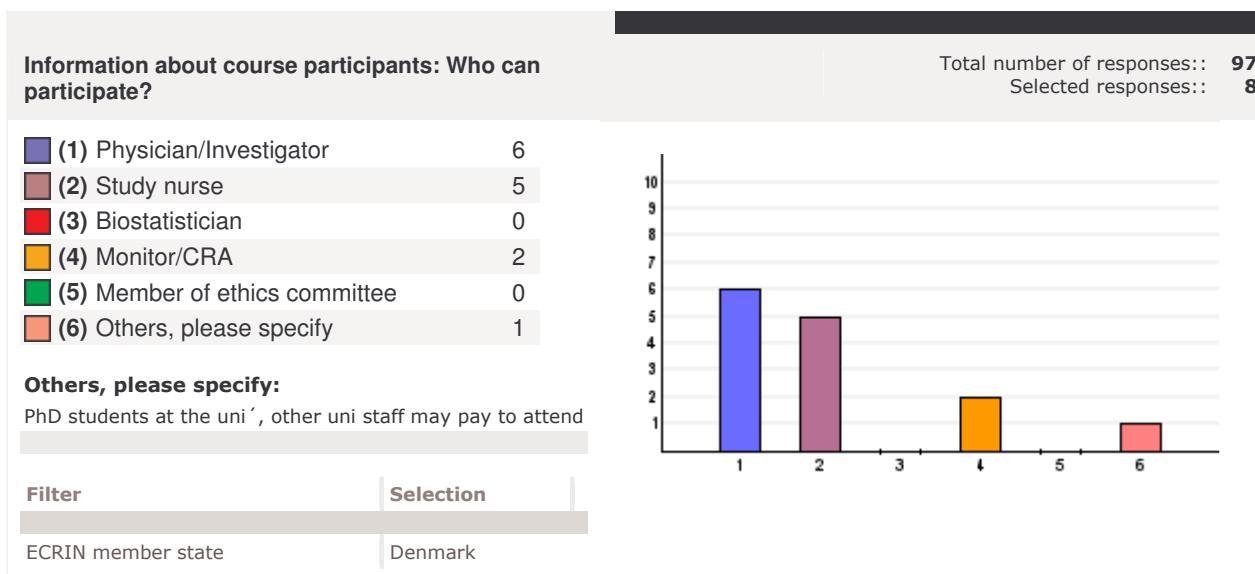
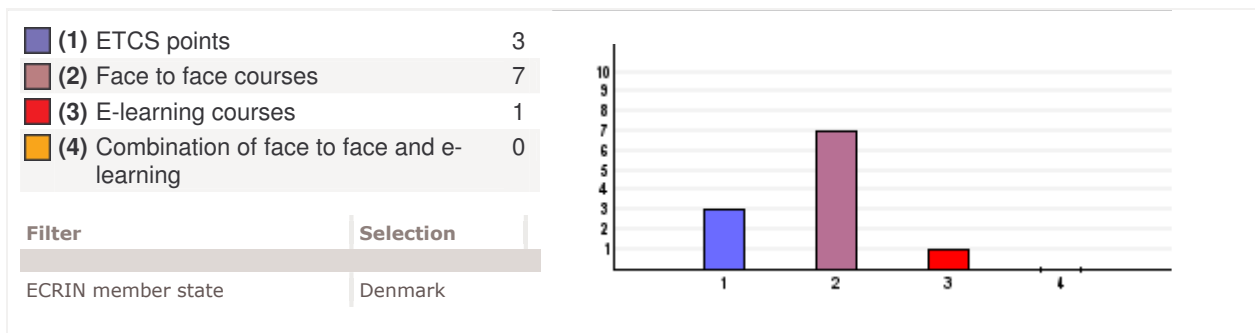
Course arena:

Total number of responses: 97
Selected responses: 8

(1) National 8
 (2) International 0
 (3) Both national and international 0

Filter	Selection





Education)

(4) Yes. Accredited according to the following system (please specify) 2

Yes. Accredited according to the following system (please specify):
by the Faculty of Health Sciences PhD committee

The course is a Ph.D.course at the University

Filter	Selection
ECRIN member state	Denmark

Option	Count
1	6
4	2

Finland

Name of institution providing courses for clinical research:

Total number of responses: 97
Selected responses: 7

Clinical Drug Research Graduate School (national grad. sch.)	4-8 annually; some as joint courses with other institutions
Tampere University Hospital	2
University of Kuopio, Centre Training and Development	2-3 per year, total about 25 during last 8 years
Pharmaceutical Learning Centre	1-2 days per year
Lääketietokeskus Oy / Pharmaceutical Information Centre Ltd	10
M.I.T. Consulting Ltd.	10
Turku Clinical Research Centre	2

Filter	Selection
ECRIN member state	Finland

Language of the courses

Total number of responses: 97
Selected responses: 7

(1) English 3

(2) Other, please specify 7

Other, please specify: Finnish

Filter	Selection
ECRIN member state	Finland

Option	Count
1	3
2	7

Course arena:

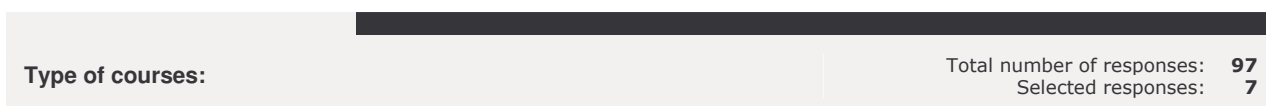
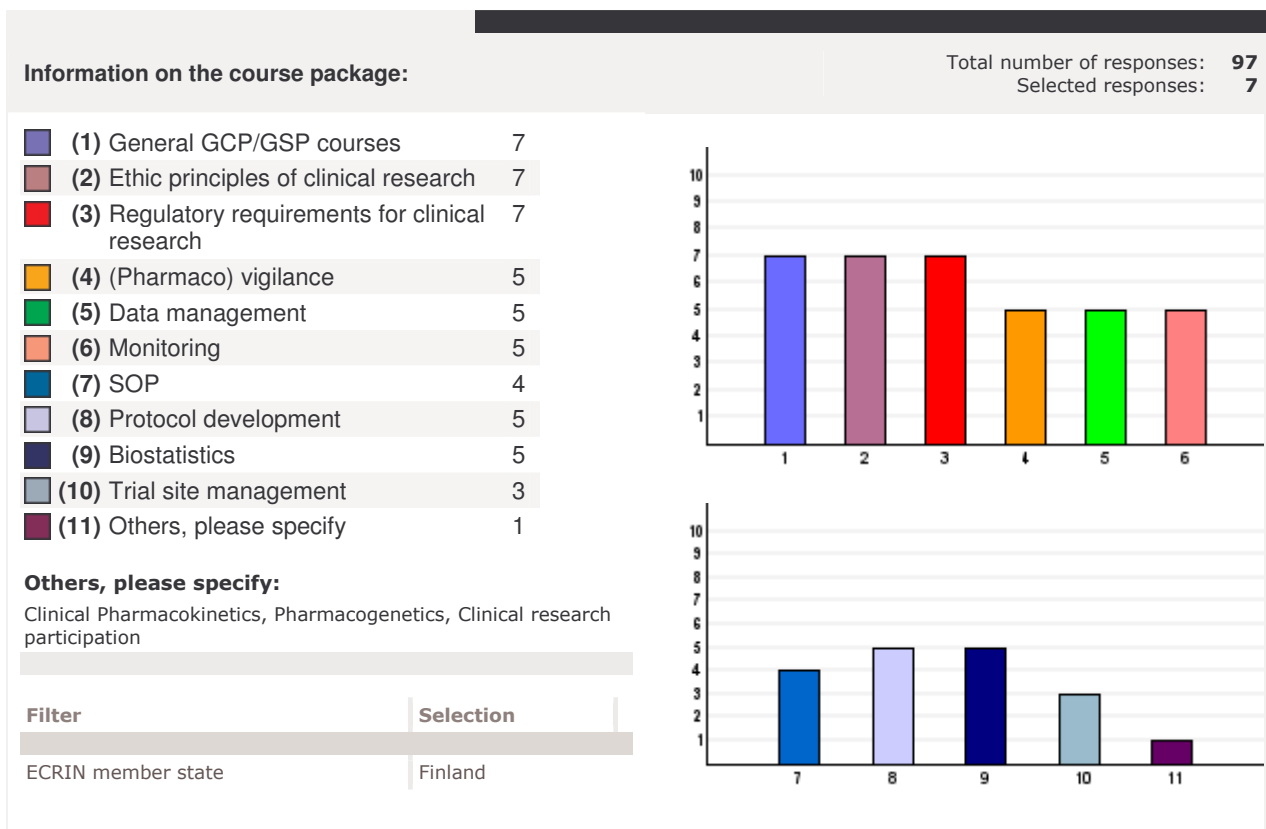
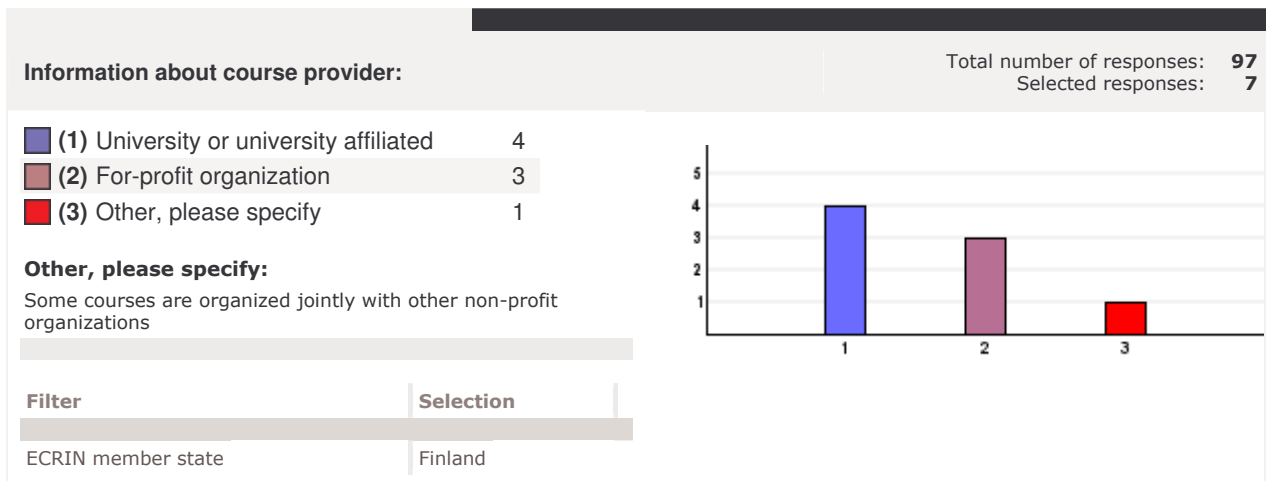
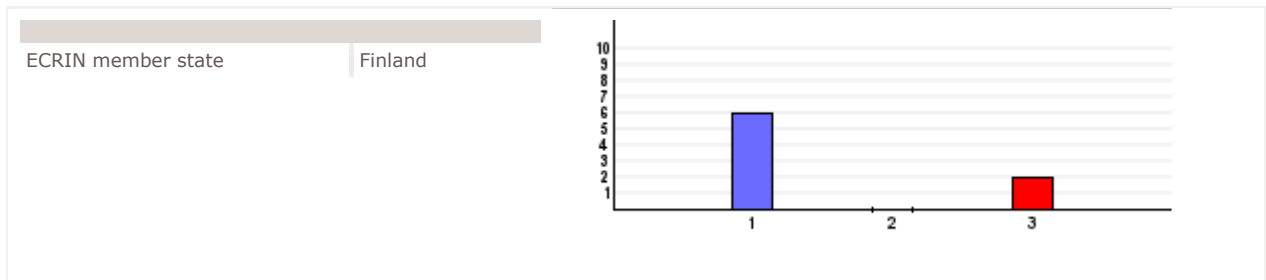
Total number of responses: 97
Selected responses: 7

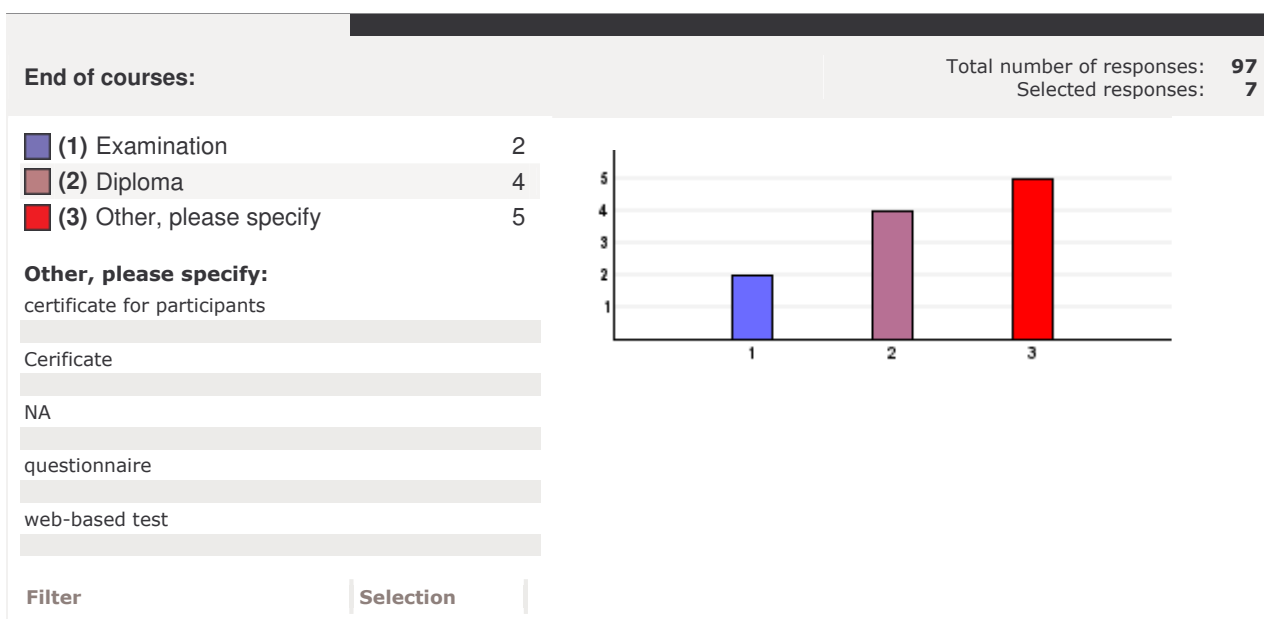
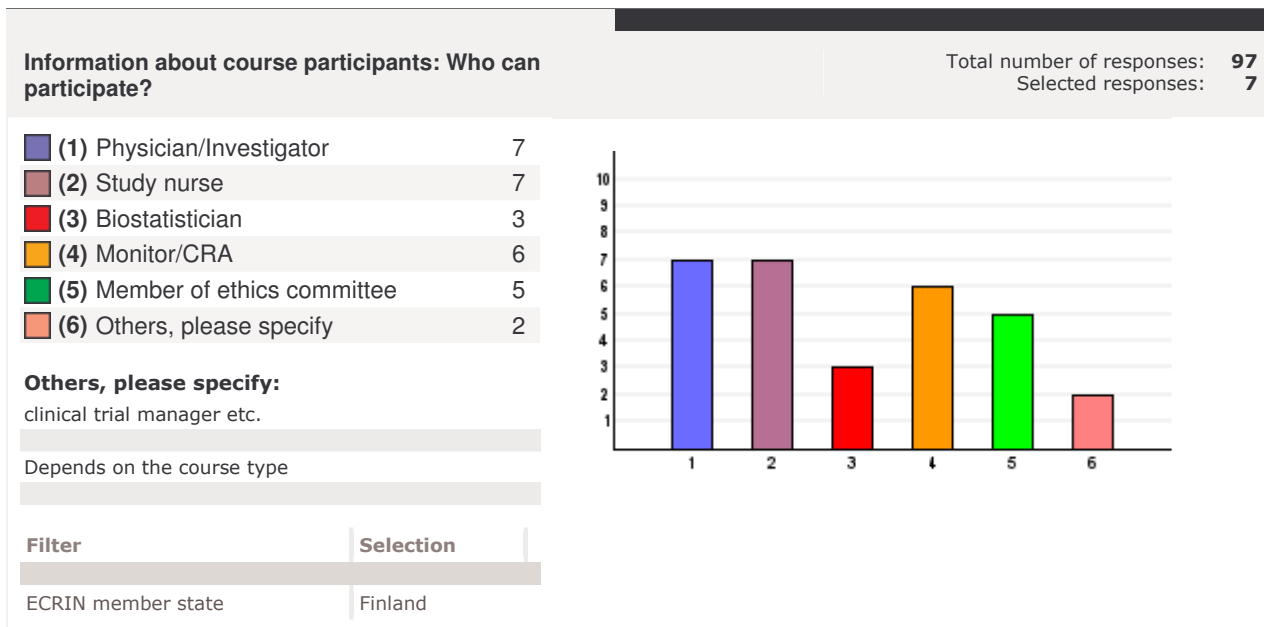
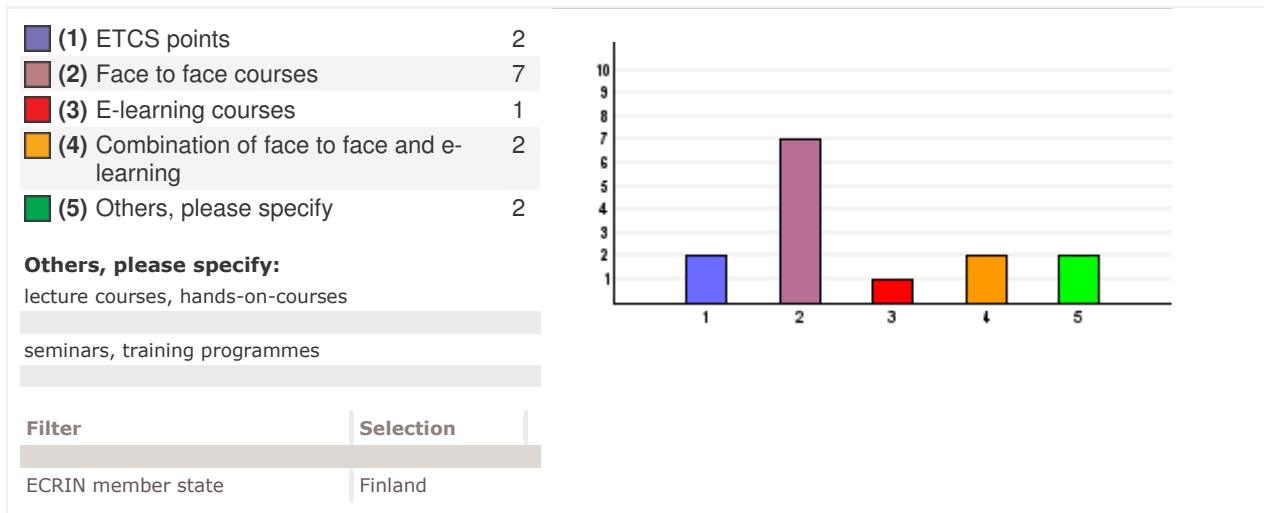
(1) National 6

(2) International 0

(3) Both national and international 2

Filter	Selection
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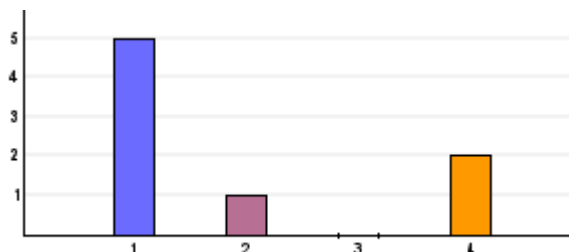


ECRIN member state | Finland

Are the courses accredited?

Total number of responses: **97**
Selected responses: **7**

- (1) No. 5
- (2) Yes. Accreditation is made by a third party. 1
- (3) Yes. Accreditation is made according to CME (Continuing Medical Education) 0
- (4) Yes. Accredited according to the following system (please specify) 2



Yes. Accredited according to the following system (please specify):

Most of the courses are accredited by Medical faculties

University of Kuopio complies with the requirements of the standard SFS-EN ISO 9001:2000

Filter | Selection

ECRIN member state | Finland

France

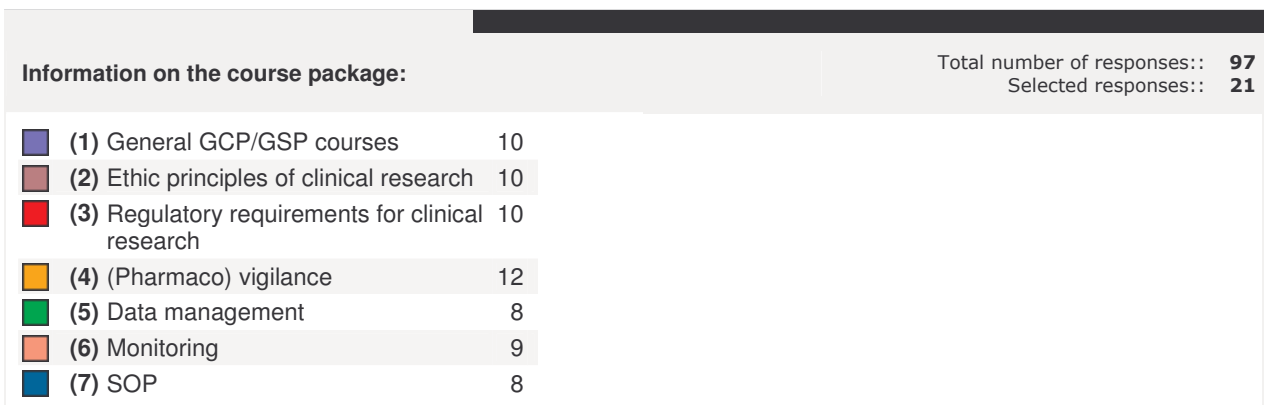
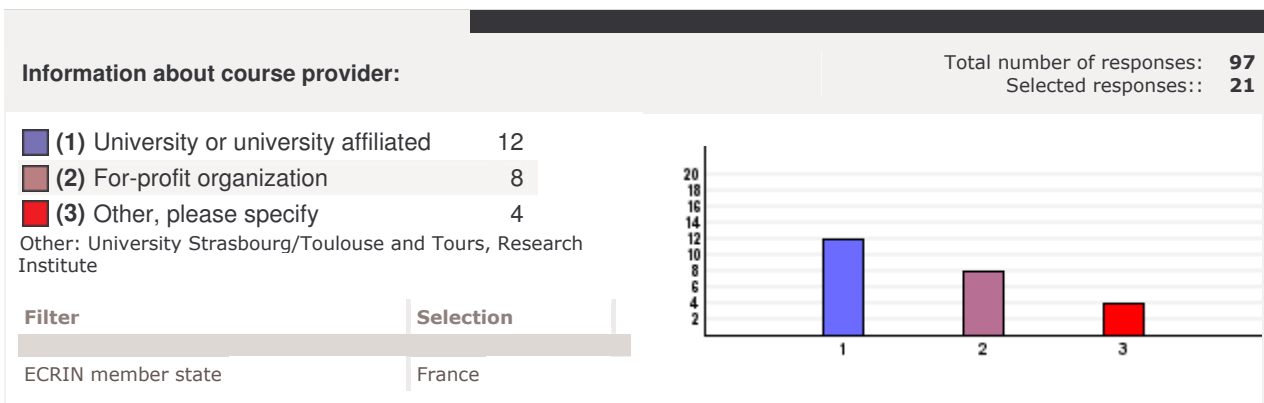
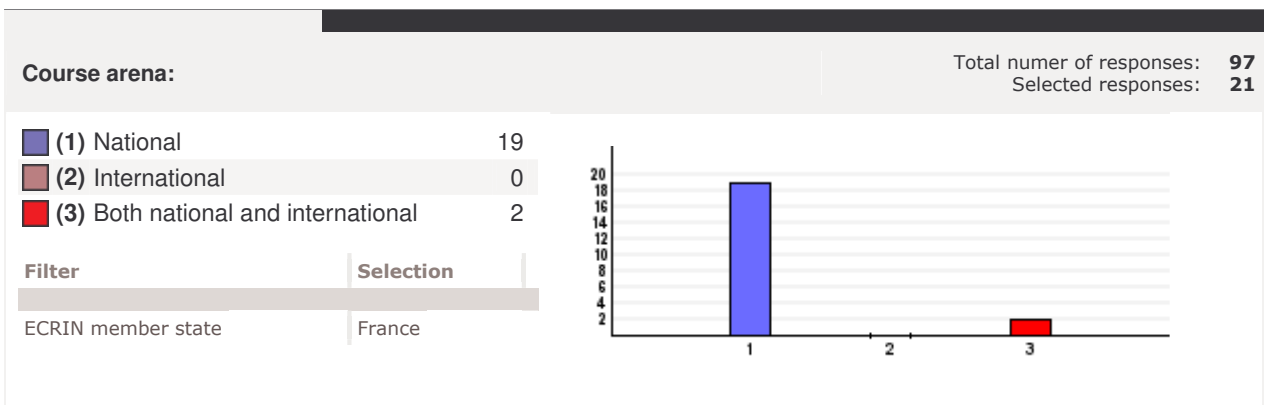
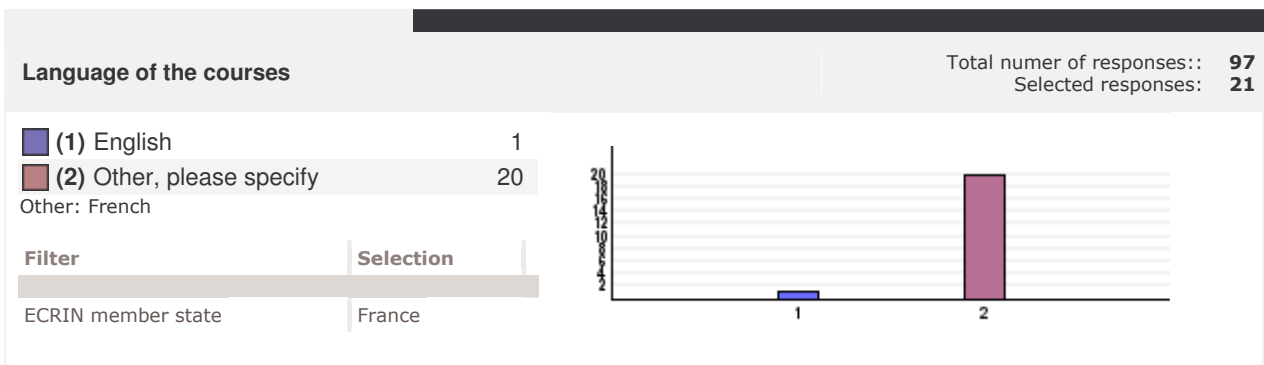
The data presented below represents only a selection of the trainings that are available in France. The CenGEPS, a public-private partnership organisation which objective is to support coordination and management of commercial studies in public hospitals or networks has performed a survey on the training in clinical research available in France (<http://www.cengeps.fr/spip.php?rubrique9>).

Name of institution providing courses for clinical research and number of courses provided:

Total number of responses: **97**
Selected responses: **21**

For drug consulting	7
Advanced Drug Development services	5
SupSante	2
Clinact	3
University Toulouse	1
University Bordeaux 2 Institut de Santé Publique d'Epidemiol	1
Medical University Lyon	1
Inserm	1
University Angers	1
University Franche-Comté	1
University Paris 12 Val de Marne	1
University Paris VI	1
Paris 6-7-11/Bordeaux 2/Lyon 1/Marseille 2/Nantes/St Etienne	3
University Paris 7	6

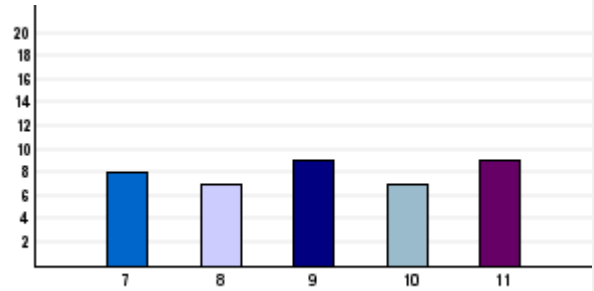
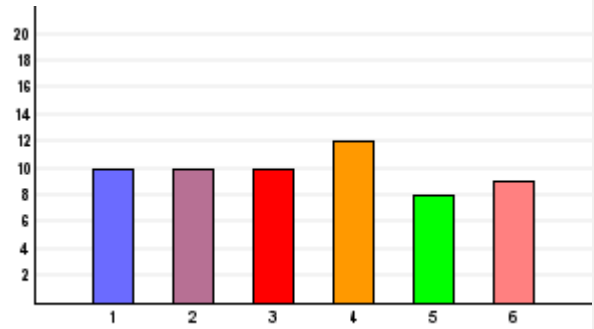
Filter	Selection
ECRIN member state	France



(8) Protocol development	7
(9) Biostatistics	9
(10) Trial site management	7
(11) Others, please specify	9

Others: specific aspects of biotherapy and genetic studies+ management of biological samples, European Diploma in Pharmaceutical Medicines, Methodology in clinical research and epidemiology, Training of Clinical Research Technicians, Training leading to a qualification of Clinical Research Assistant, training for data managers

Filter	Selection
ECRIN member state	France

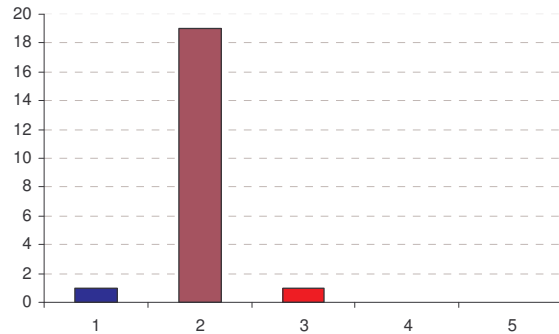


Type of courses:

Total number of responses: 97
Selected responses: 21

(1) ETCS points	1
(2) Face to face courses	19
(3) E-learning courses	1
(4) Combination of face to face and e-learning	0
(5) Others, please specify	0

Filter	Selection
ECRIN member state	France

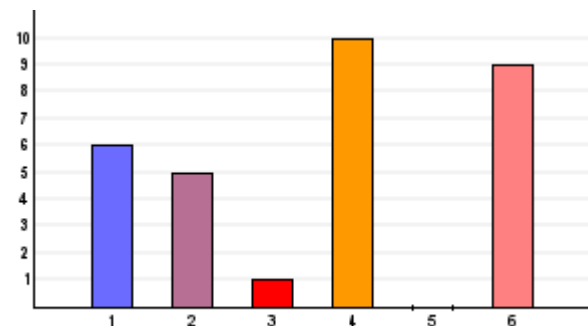


Information about course participants: Who can participate?

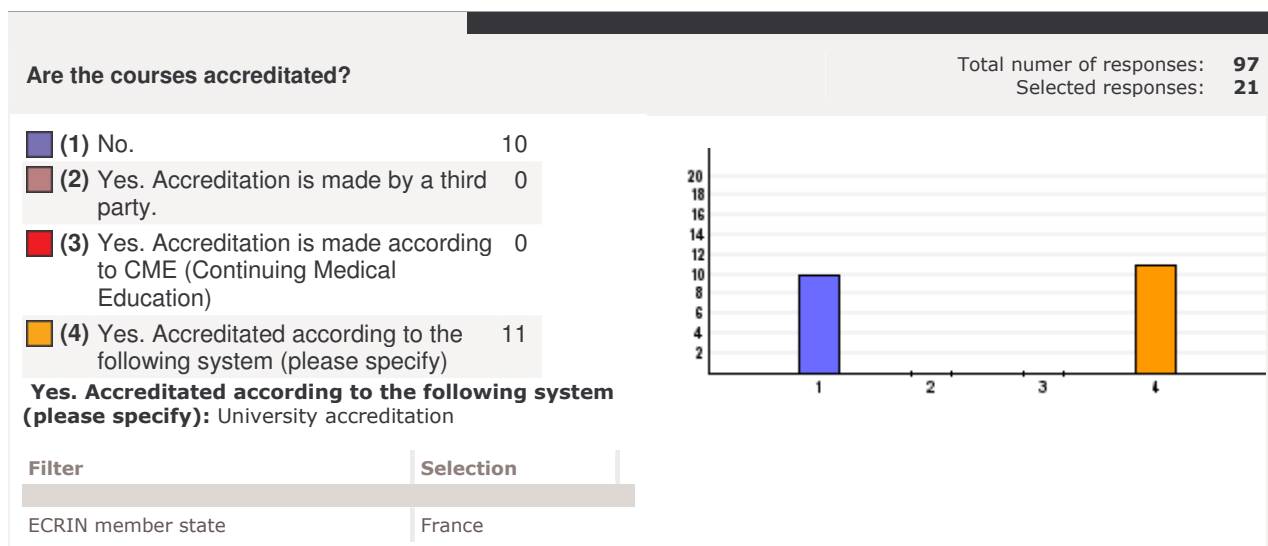
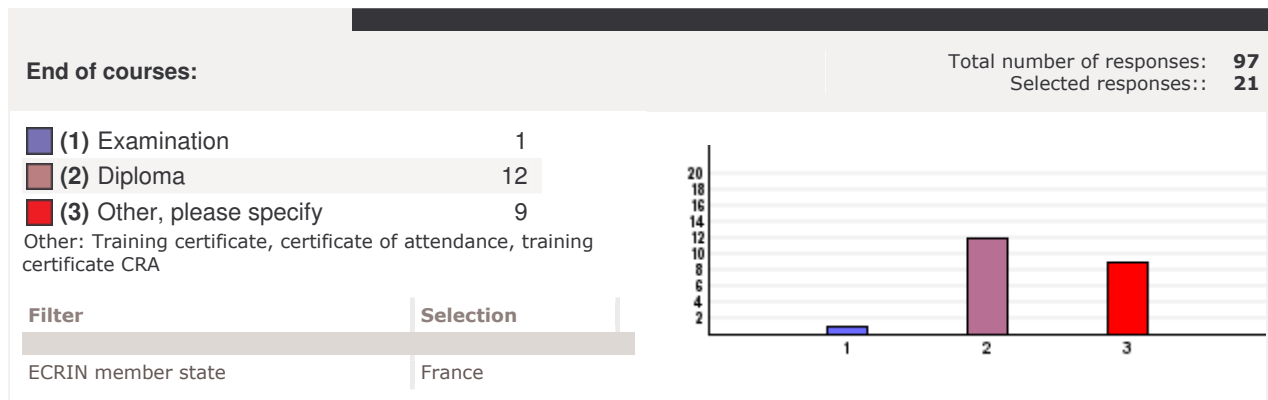
Total number of responses: 97
Selected responses: 21

(1) Physician/Investigator	6
(2) Study nurse	5
(3) Biostatistician	1
(4) Monitor/CRA	10
(5) Member of ethics committee	0
(6) Others, please specify	9

Others: Clinical research technician, management of biological samples, data managers or people who want to work in data management, Health professionals, people who work or want to work in pharmacovigilance



Filter	Selection
ECRIN member state	France



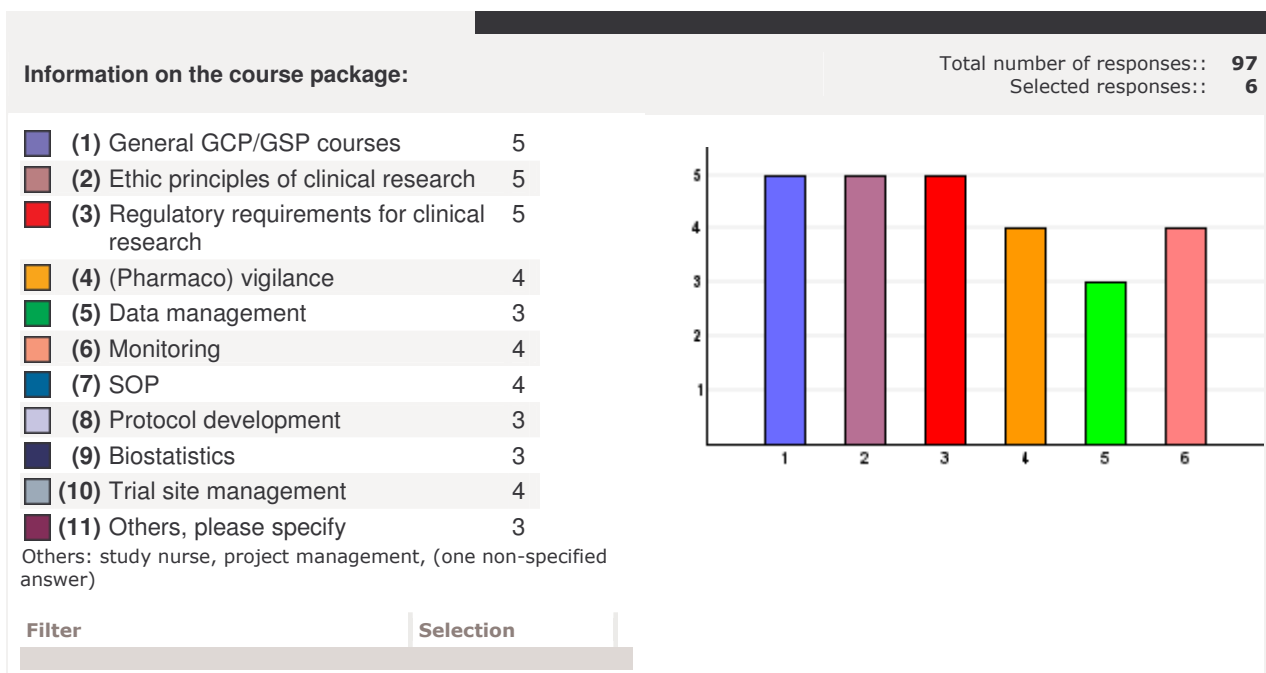
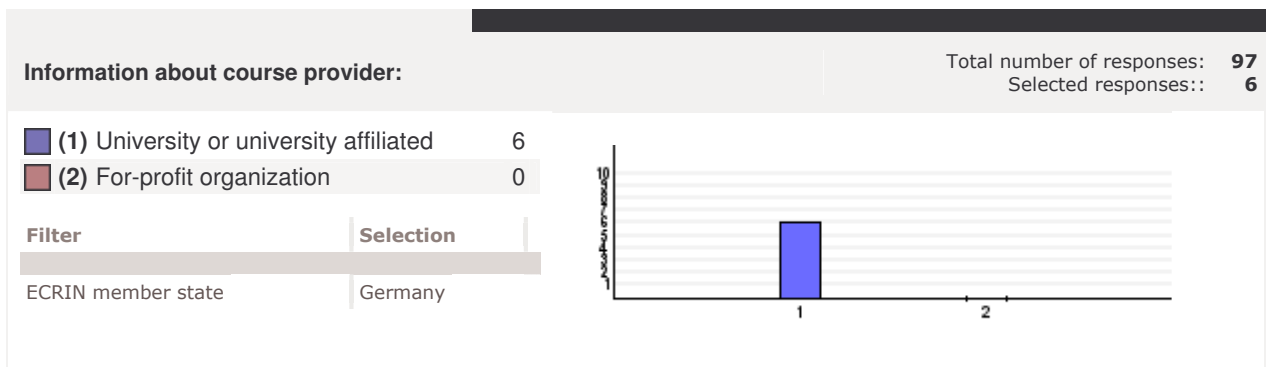
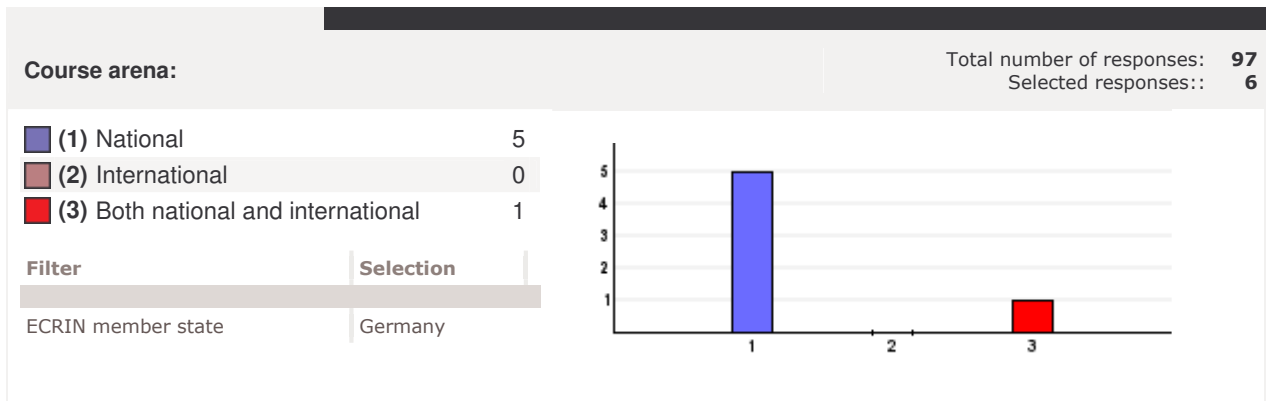
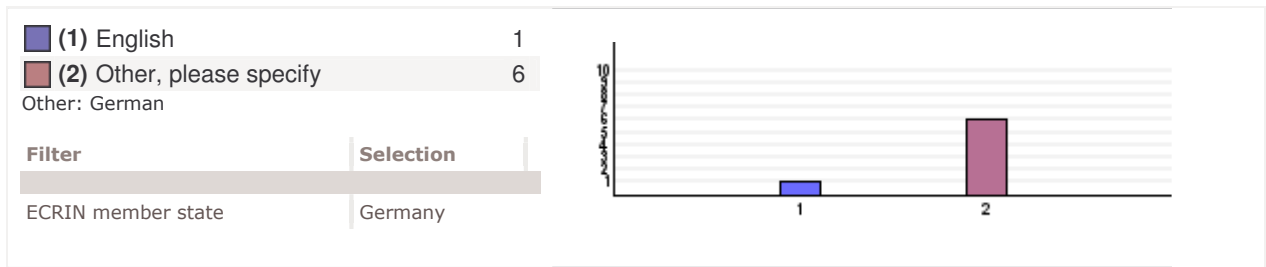
Germany

Name of institution providing courses for clinical research and number of courses provided: Total number of responses: **97**
Selected responses: **6**

Zentrum für Klinische Studien Münster	2 basic courses for investigators/year, several advanced courses
KKS Mainz/ Koordinierungszentrum	6
KKS Charité	six
KKS Dresden, Faculty of Medicine	5
Clinical Trials Center	10
ZKS Essen	2

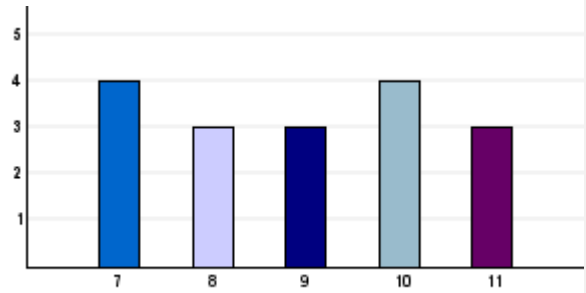
Filter	Urval
ECRIN member state	Germany

Language of the courses Total number of responses: **97**
Selected responses: **6**



ECRIN member state

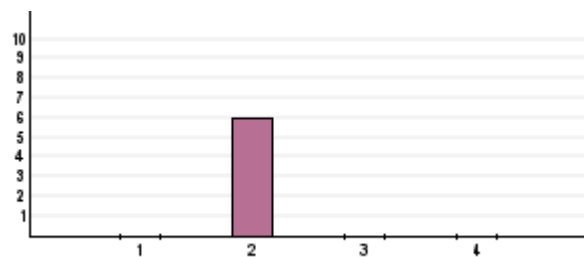
Germany



Type of courses:

Total number of responses: 97
Selected responses: 6

(1) ETCS points	0
(2) Face to face courses	6
(3) E-learning courses	0
(4) Combination of face to face and e-learning	0



Filter

Selection

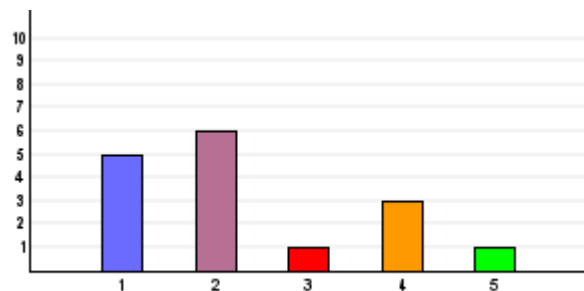
ECRIN member state

Germany

Information about course participants: Who can participate?

Total number of responses: 97
Selected responses: 6

(1) Physician/Investigator	5
(2) Study nurse	6
(3) Biostatistician	1
(4) Monitor/CRA	3
(5) Member of ethics committee	1



Filter

Selection

ECRIN member state

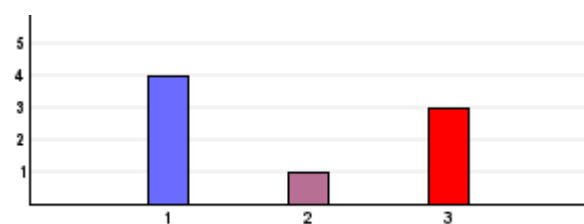
Germany

End of courses:

Total number of responses: 97
Selected responses: 6

(1) Examination	4
(2) Diploma	1
(3) Other, please specify	3

Other: Certificate, cert. of attendance



Filter

Selection

ECRIN member state

Germany

Are the courses accredited? Total number of responses:: **97**
Selected responses:: **6**

<input type="checkbox"/> (1) No.	0
<input type="checkbox"/> (2) Yes. Accreditation is made by a third party.	2
<input type="checkbox"/> (3) Yes. Accreditation is made according to CME (Continuing Medical Education)	3
<input type="checkbox"/> (4) Yes. Accredited according to the following system (please specify)	2

Yes. Accredited according to the following system (please specify):
Courses are following the curriculum of the KKS-network

KKS Network (Germany)

Filter	Selection
ECRIN member state	Germany

Hungary

Name of institution providing courses for clinical research and number of courses provided: Total number of responses:: **97**
Selected responses:: **1**

university clinics in Hungary one per year

Filter	Urval
ECRIN member state	Hungary

Language of the courses Total number of responses:: **97**
Selected responses:: **1**

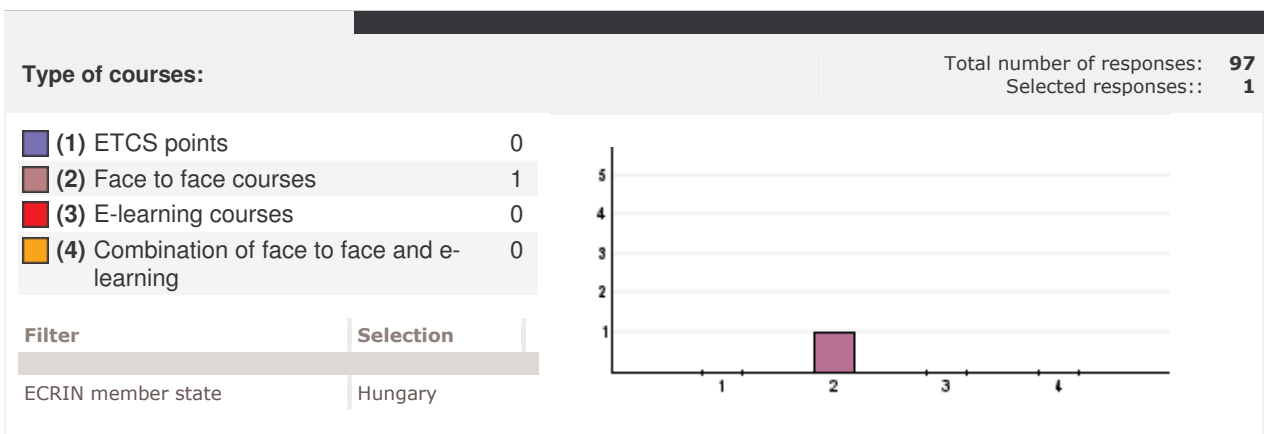
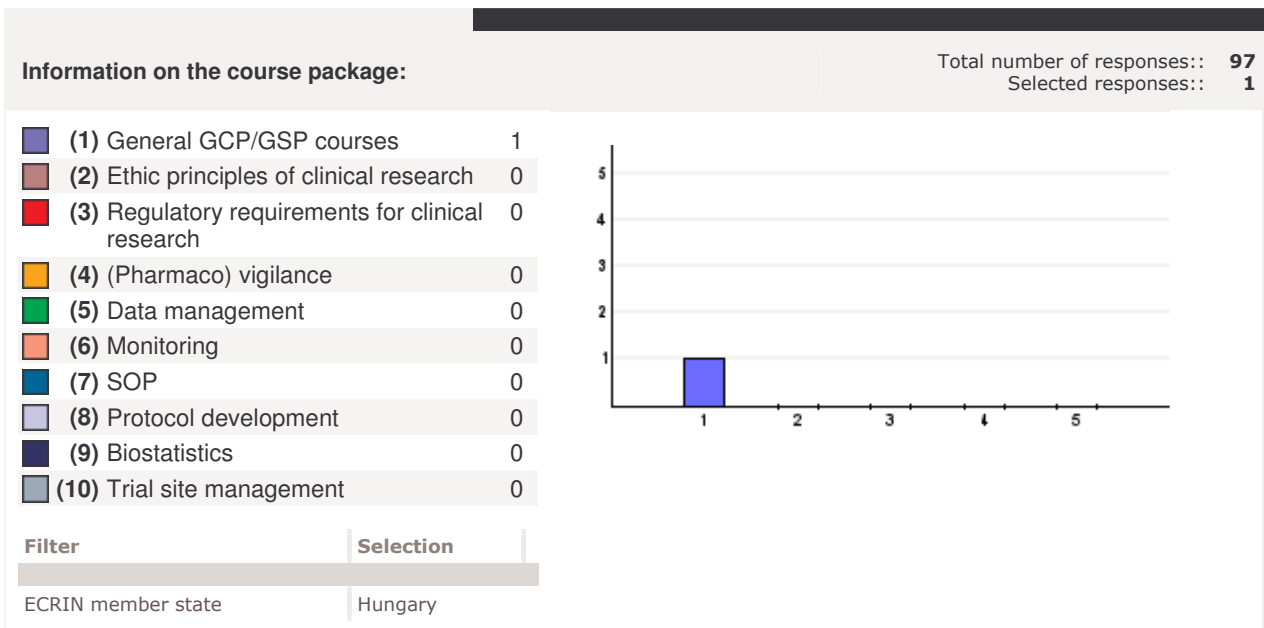
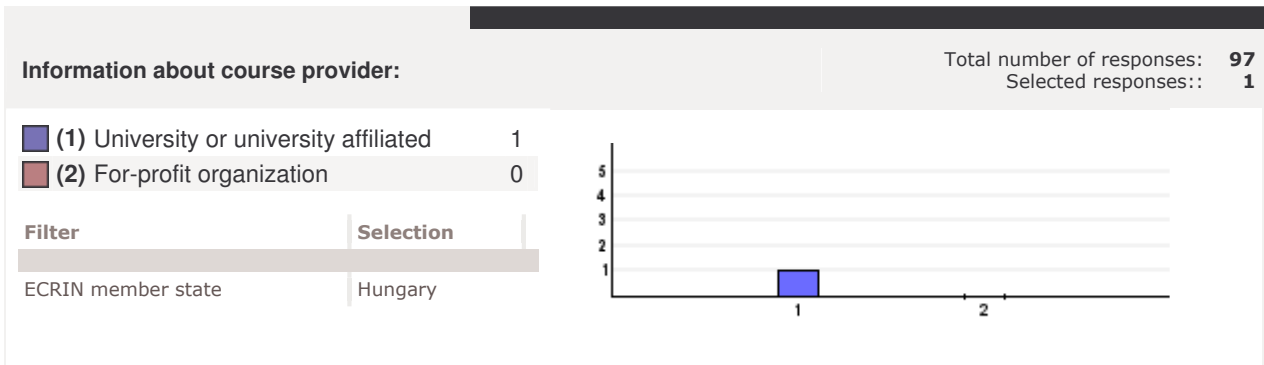
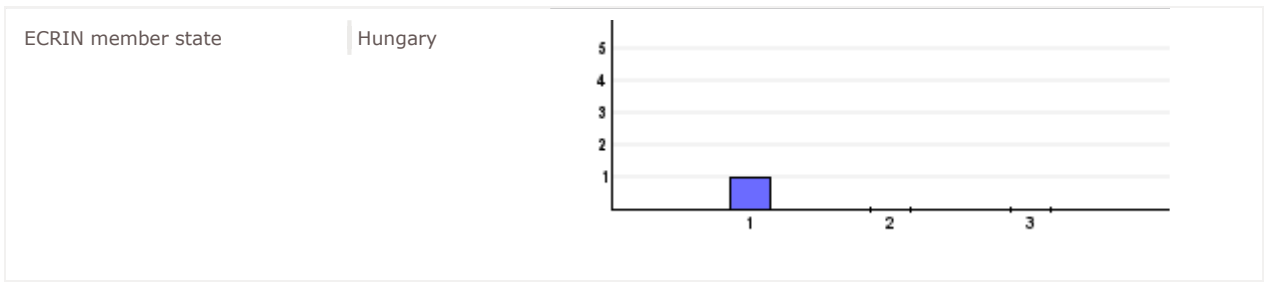
<input type="checkbox"/> (1) English	1
--------------------------------------	---

Filter	Selection
ECRIN member state	Hungary

Course arena: Total number of responses:: **97**
Selected responses:: **1**

<input type="checkbox"/> (1) National	1
<input type="checkbox"/> (2) International	0
<input type="checkbox"/> (3) Both national and international	0

Filter	Selection

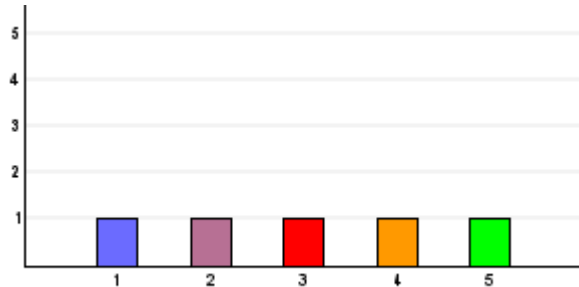


Information about course participants: Who can participate?

Total number of responses: **97**
Selected responses: **1**

<input type="checkbox"/> (1) Physician/Investigator	1
<input type="checkbox"/> (2) Study nurse	1
<input type="checkbox"/> (3) Biostatistician	1
<input type="checkbox"/> (4) Monitor/CRA	1
<input type="checkbox"/> (5) Member of ethics committee	1

Filter	Selection
ECRIN member state	Hungary

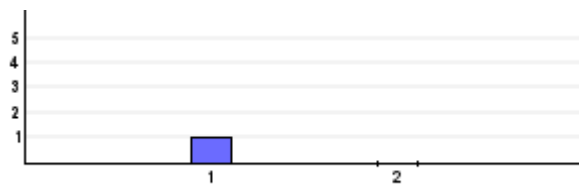


End of courses:

Total number of responses: **97**
Selected responses: **1**

<input type="checkbox"/> (1) Examination	1
<input type="checkbox"/> (2) Diploma	0

Filter	Selection
ECRIN member state	Hungary

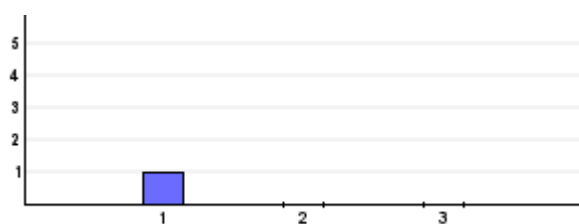


Are the courses accredited?

Total number of responses: **97**
Selected responses: **1**

<input type="checkbox"/> (1) No.	1
<input type="checkbox"/> (2) Yes. Accreditation is made by a third party.	0
<input type="checkbox"/> (3) Yes. Accreditation is made according to CME (Continuing Medical Education)	0

Filter	Selection
ECRIN member state	Hungary



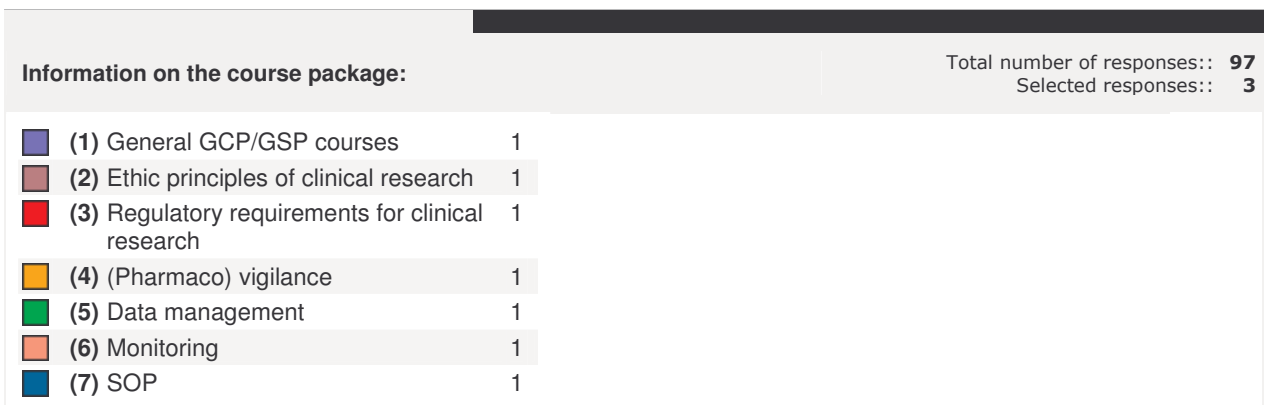
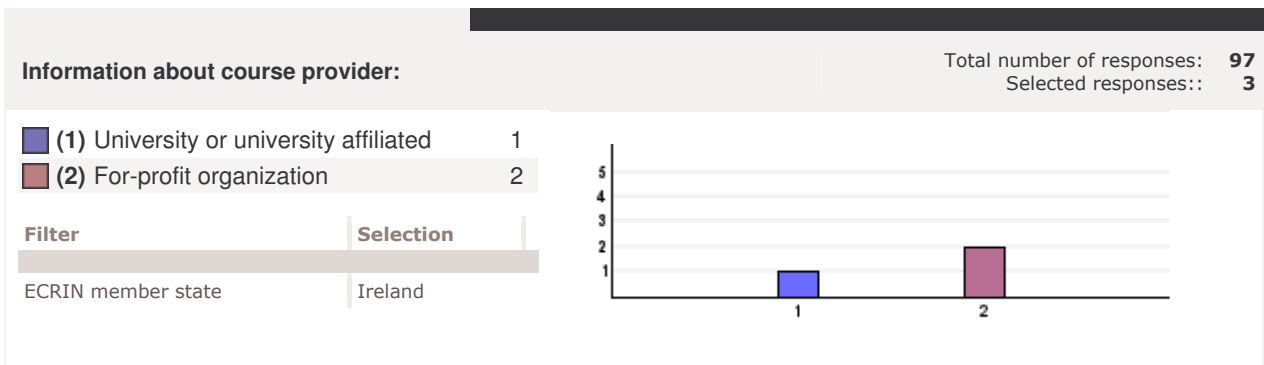
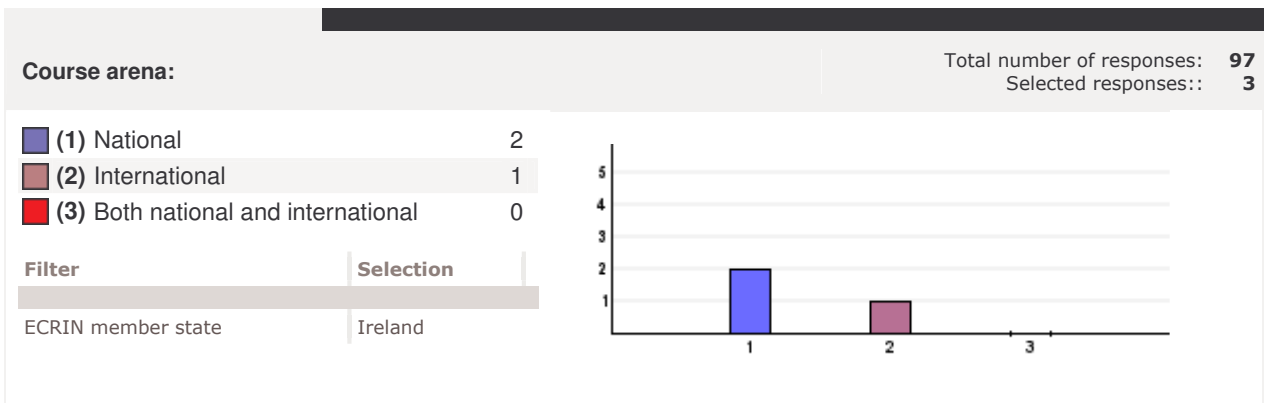
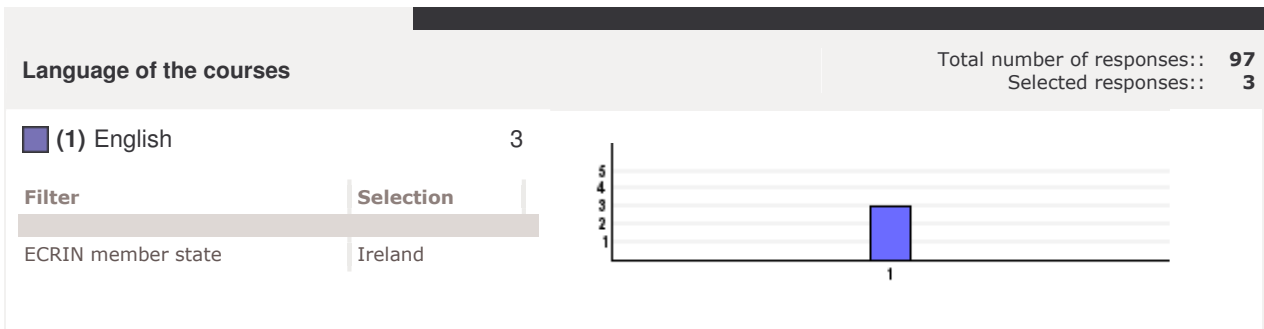
Ireland

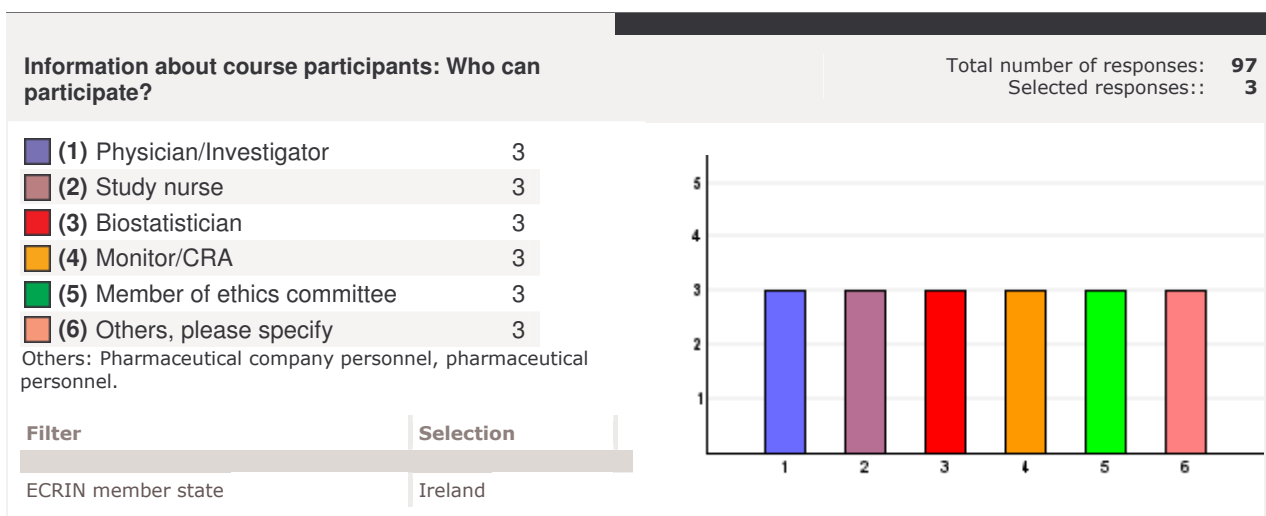
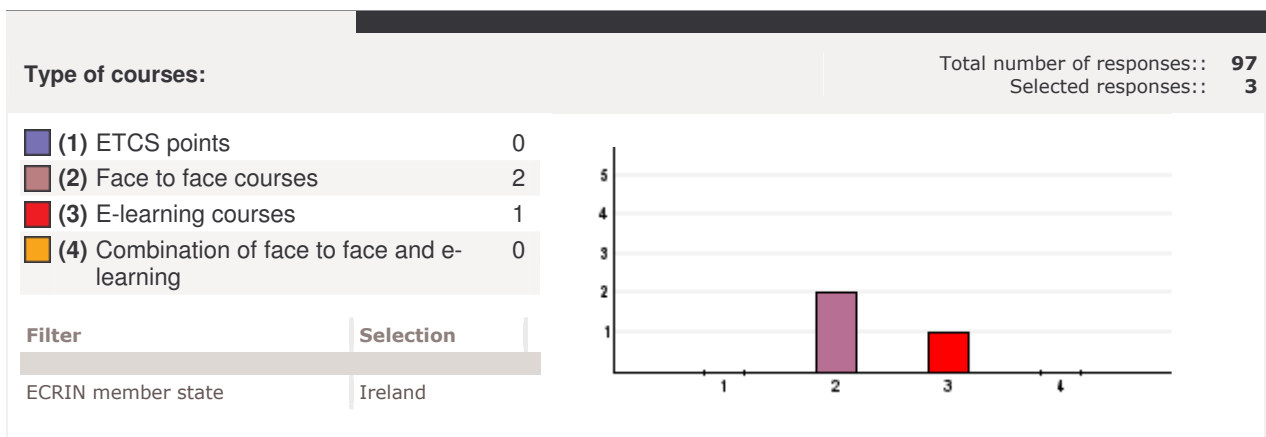
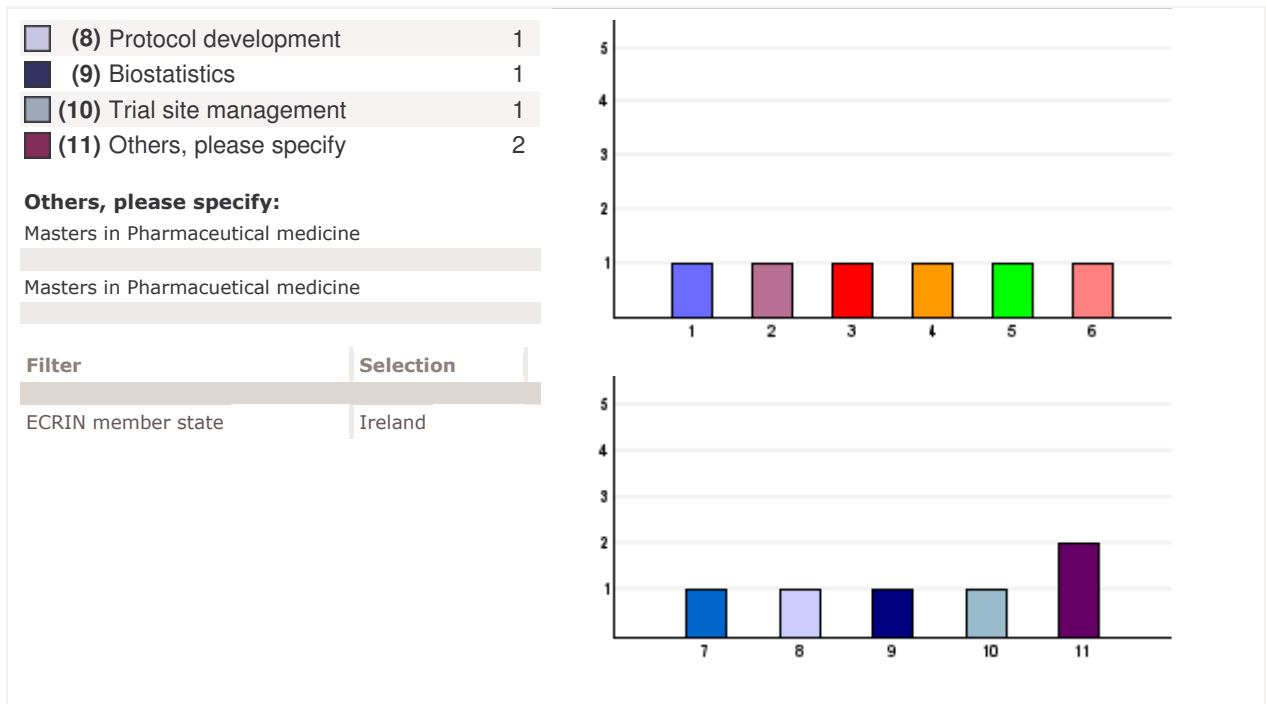
Name of institution providing courses for clinical research and number of courses provided:

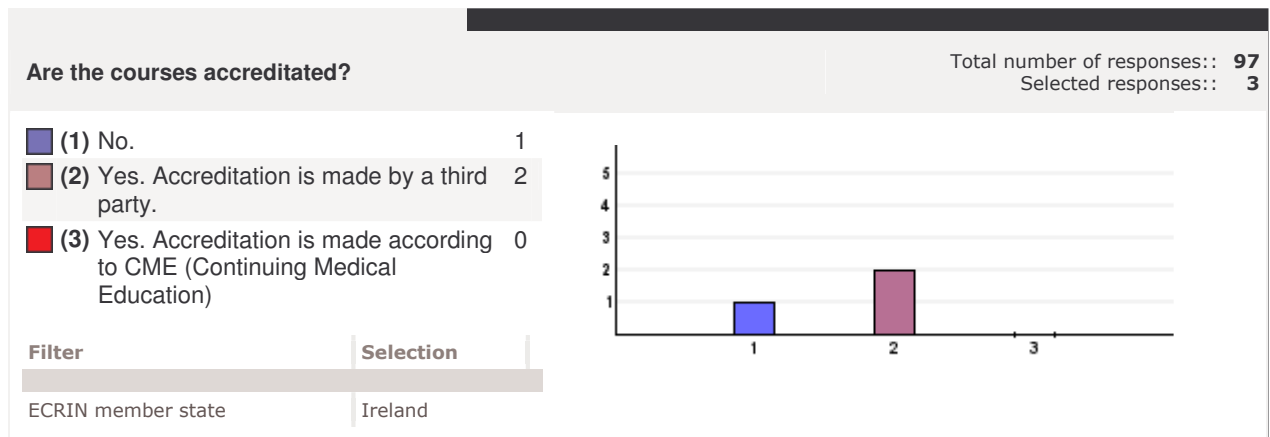
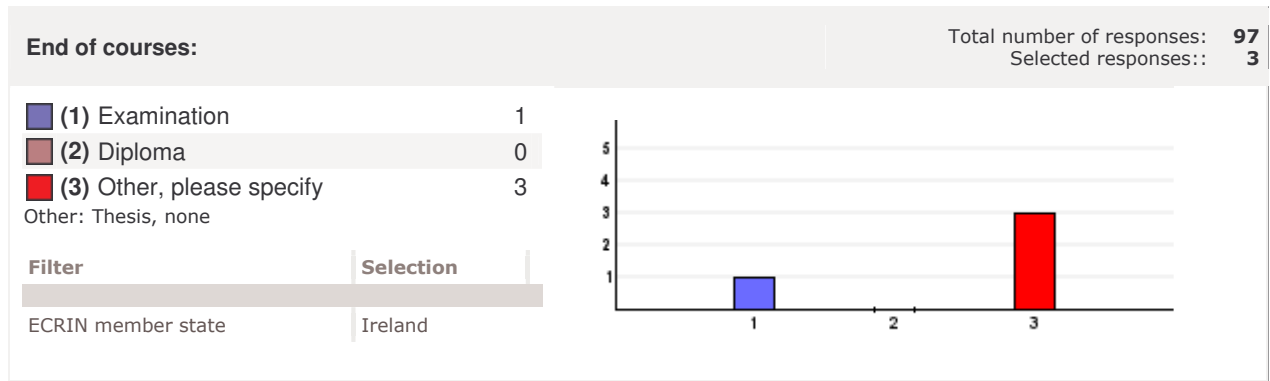
Total number of responses: **97**
Selected responses: **3**

Scope Clinical research	4
Trinity College Dublin	1
Hibernia College	1

Filter	Urval
ECRIN member state	Ireland







Italy

Name of institution providing courses for clinical research and number of courses provided: Total number of responses: **97**
Selected responses: **20**

SSFA - società di scienze farmacologiche applicate	3/year
ISS - Istituto Superiore di Sanità	4/year
SIFO - Società Italiana di Farmacia Ospedaliera	1/year
AIFA - Agenzia Italiana del Farmaco	1
Università degli Studi dell'Insubria - Varese	1
Università degli Studi di Siena	1
SIP - società italiana di pediatria	1
Giunti O.S.	1
Associazione Culturale Pediatri	1
Università di Modena e Reggio Emilia	1
Ordine dei Medici di Roma	1
Università degli Studi di Napoli	1
ASL 12 Piemonte	1
Università degli studi di Verona	1
Università degli Studi di Pavia	1
Università degli Studi di Milano	1
FIMP - Federazione Italiana Medici Pediatri	1
C.I.R.M. Consozio Italiano per la Ricerca in Medicina	2
C.I.R.M. Consorzio Italiano per la Ricerca in Medicina	1
Istituto di Ricerche Farmacologiche "Mario Negri"	2

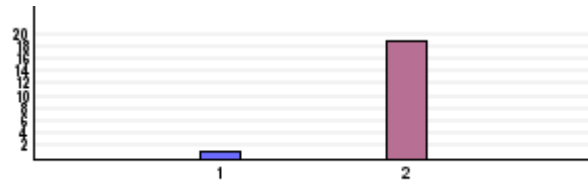
Filter	Selection
ECRIN member state	Italy

Language of the courses

Total number of responses: **97**
Selected responses: **20**

- (1) English 1
 - (2) Other, please specify 19
- Other: Italian

Filter	Selection
ECRIN member state	Italy

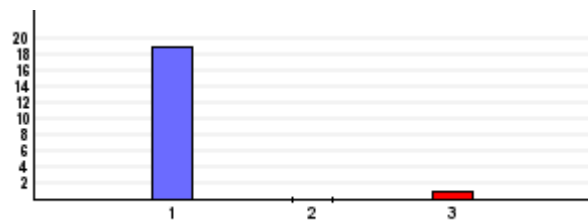


Course arena:

Total number of responses: **97**
Selected responses: **20**

- (1) National 19
- (2) International 0
- (3) Both national and international 1

Filter	Selection
ECRIN member state	Italy



Information about course provider:

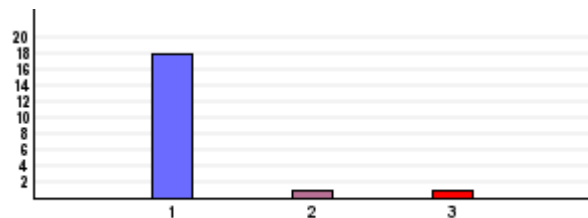
Total number of responses: **97**
Selected responses: **20**

- (1) University or university affiliated 18
- (2) For-profit organization 1
- (3) Other, please specify 1

Other, please specify:

Governmental Agency no-pofit

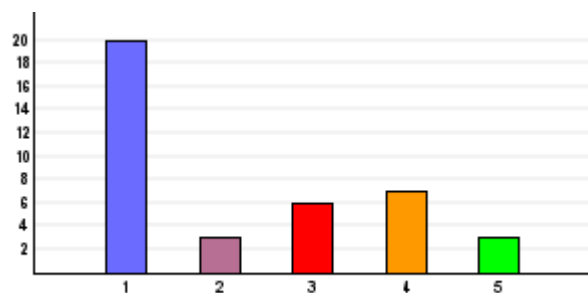
Filter	Selection
ECRIN member state	Italy

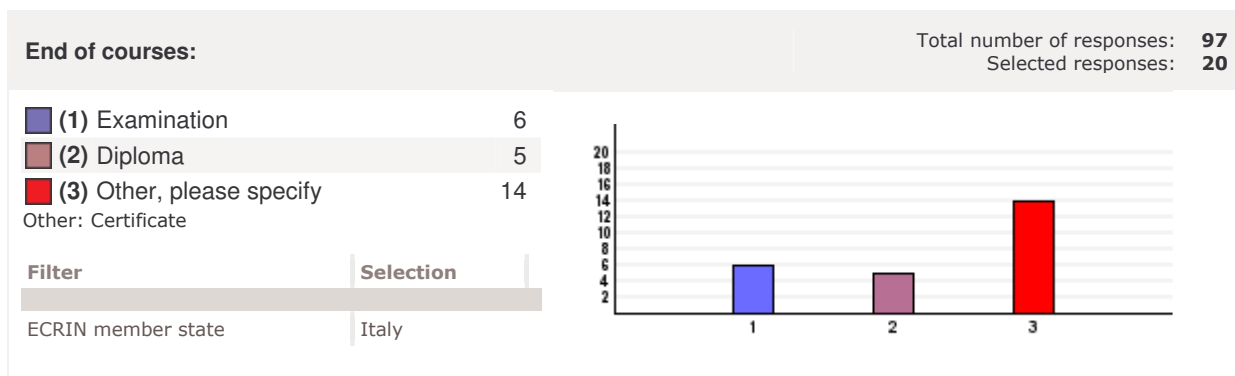
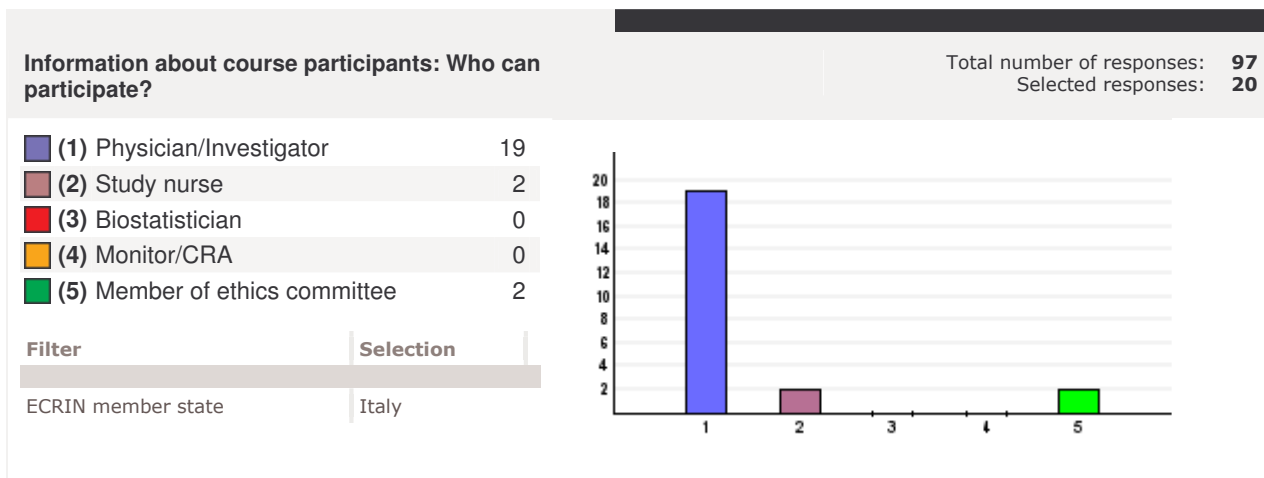
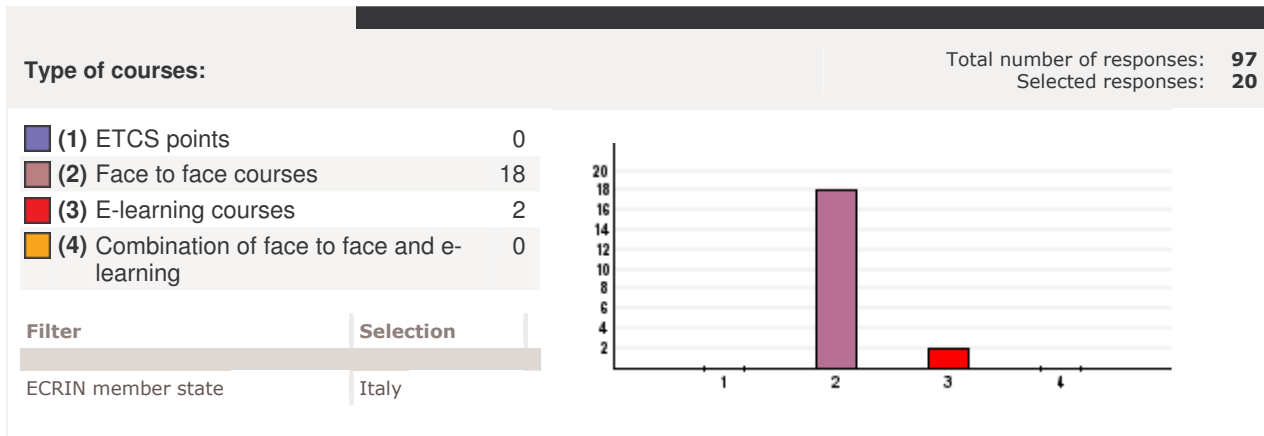
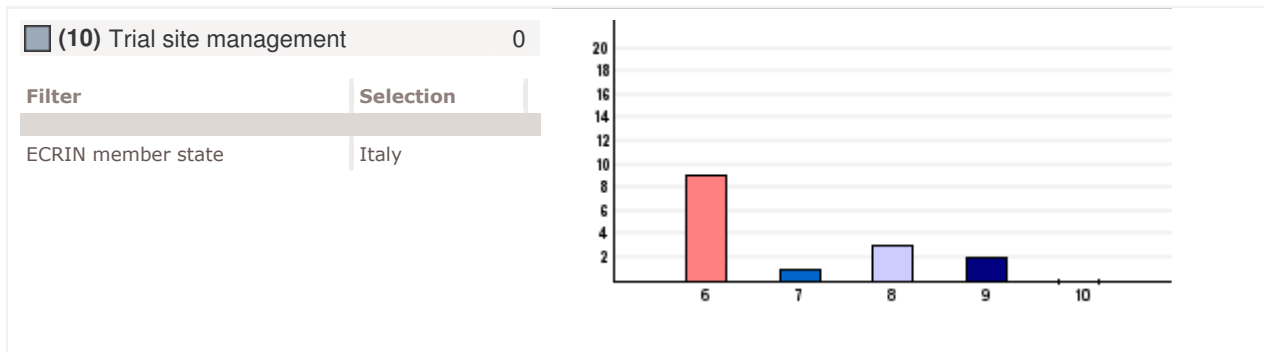


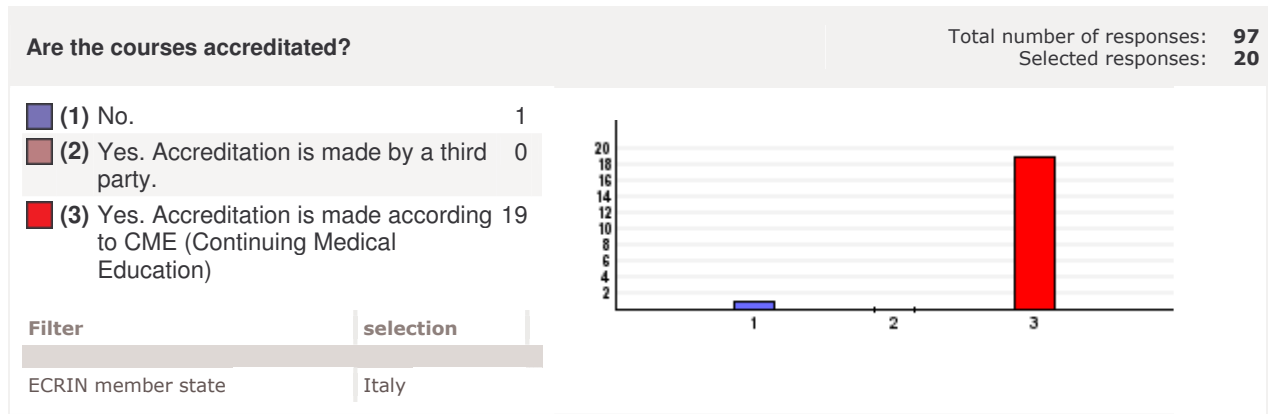
Information on the course package:

Total number of responses: **97**
Selected responses: **20**

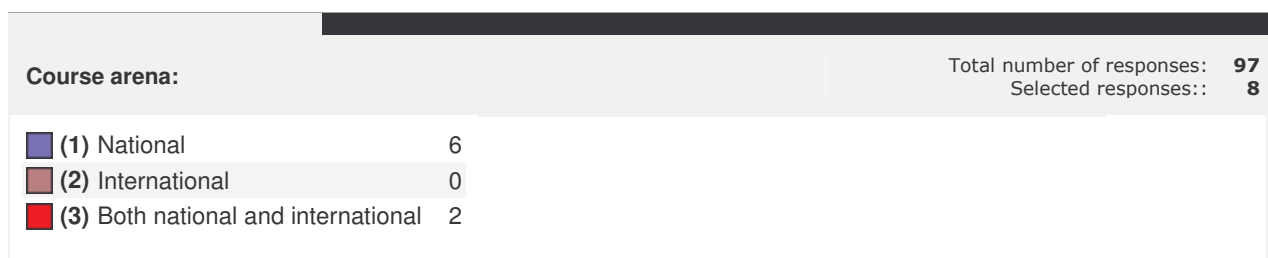
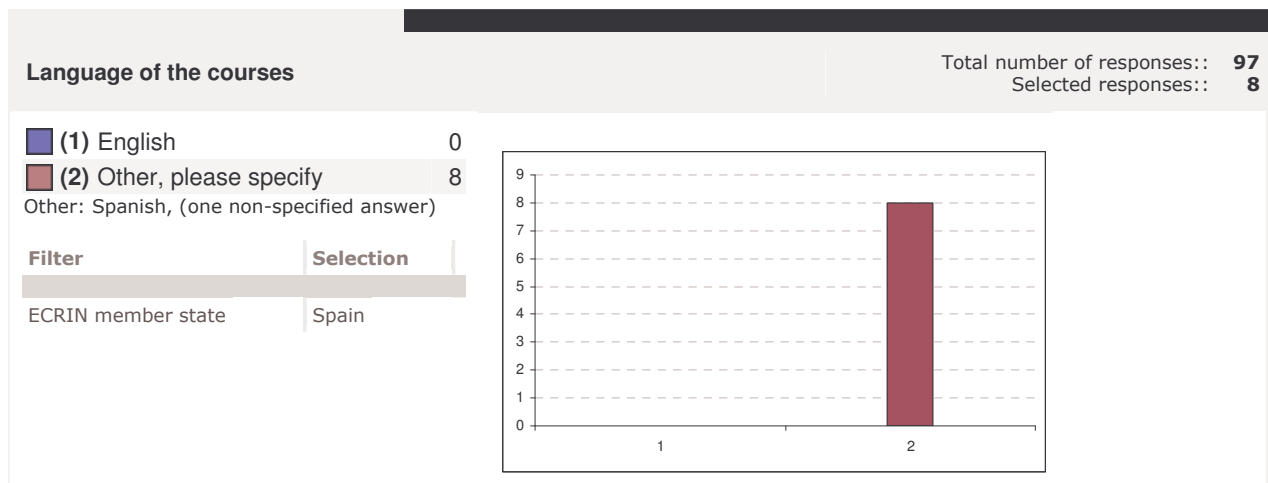
- (1) General GCP/GSP courses 20
- (2) Ethic principles of clinical research 3
- (3) Regulatory requirements for clinical research 6
- (4) (Pharmaco) vigilance 7
- (5) Data management 3
- (6) Monitoring 9
- (7) SOP 1
- (8) Protocol development 3
- (9) Biostatistics 2

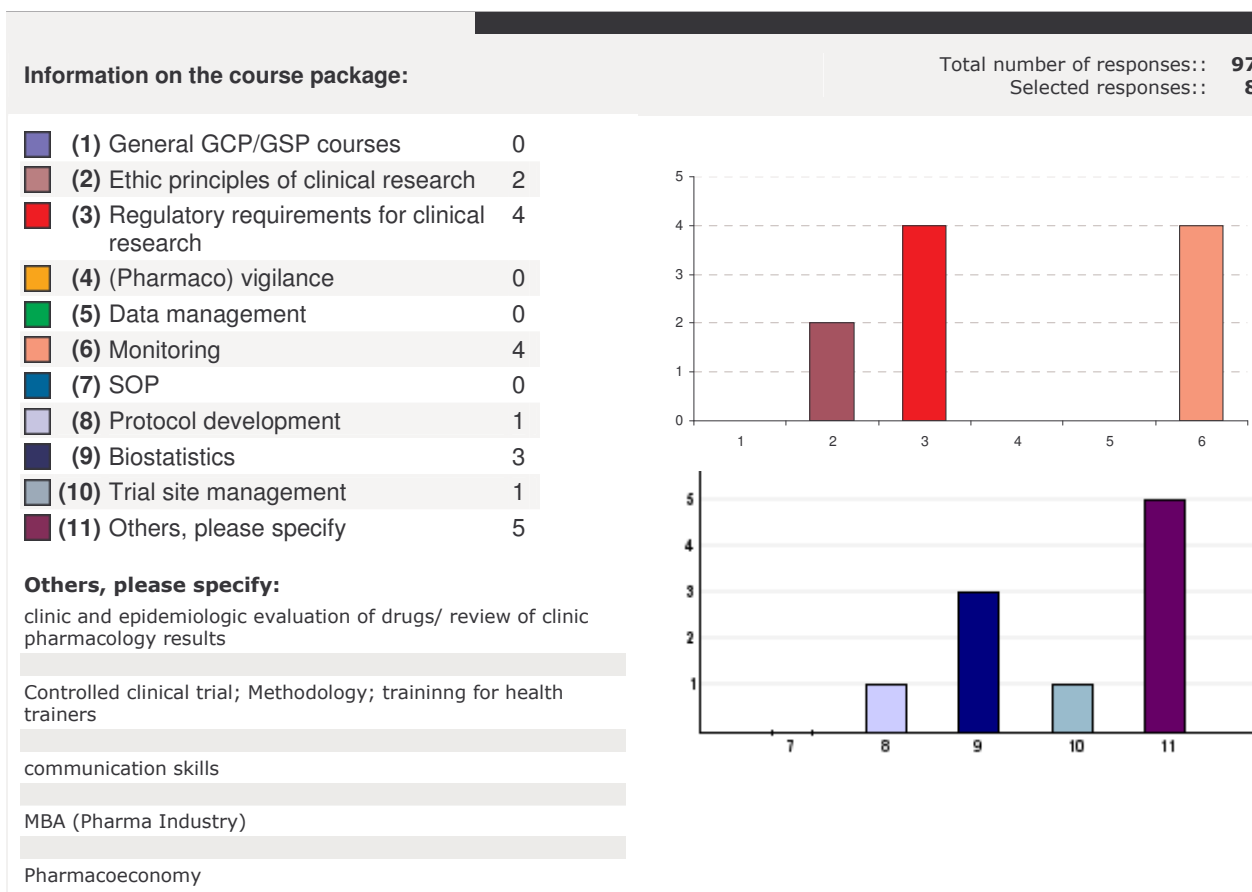
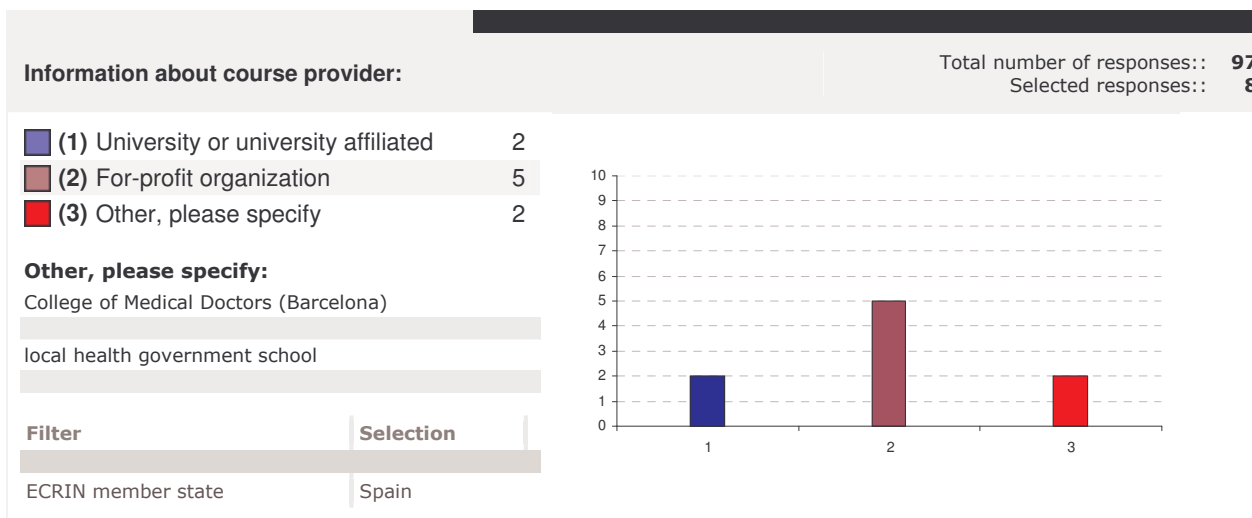
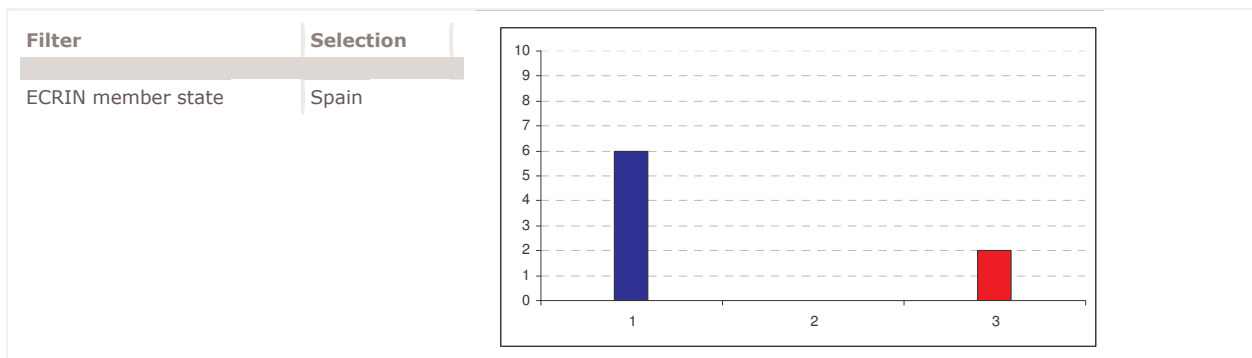




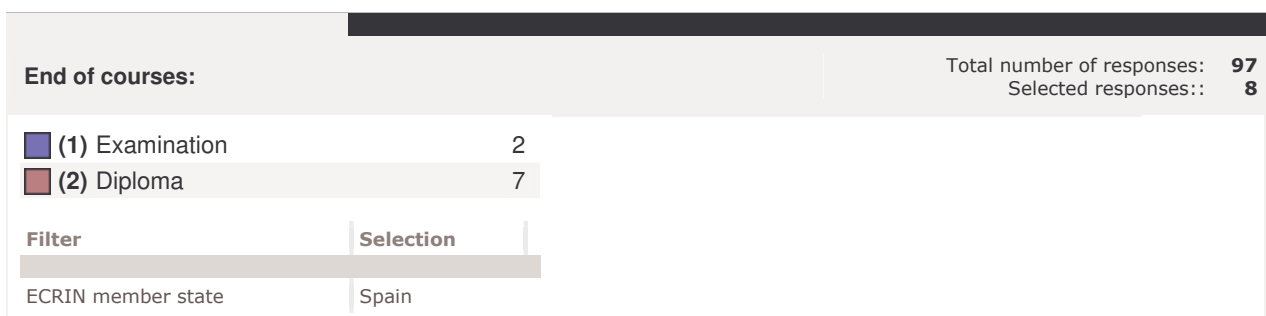
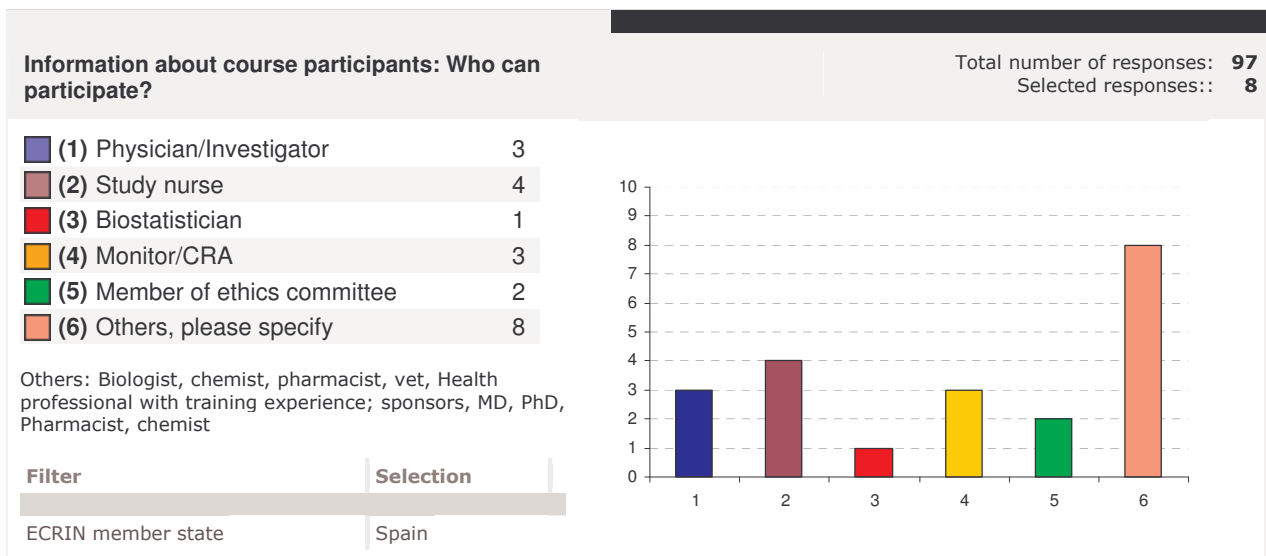
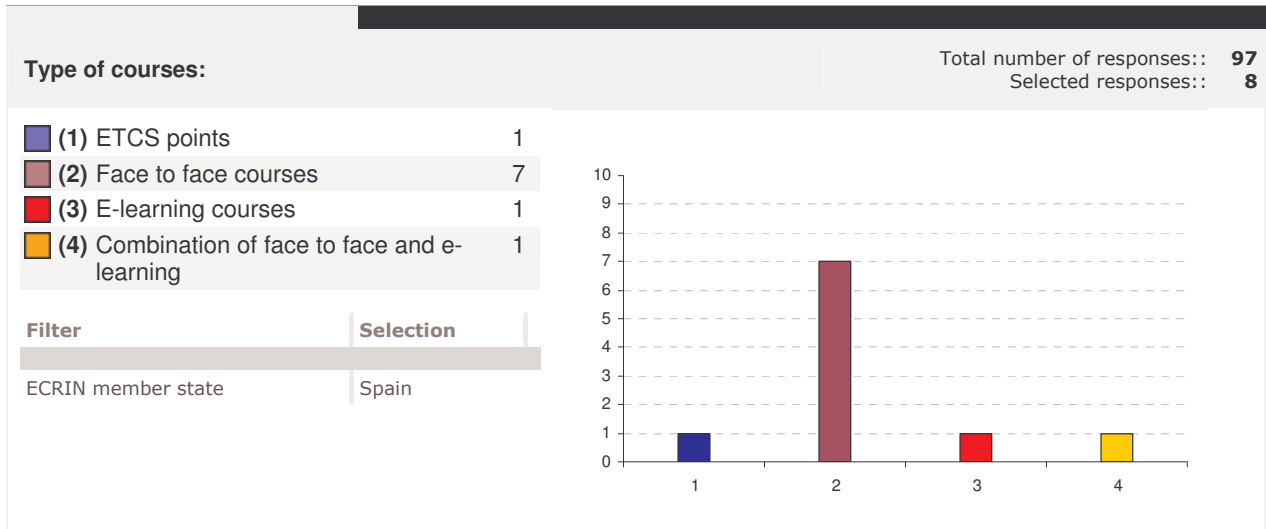


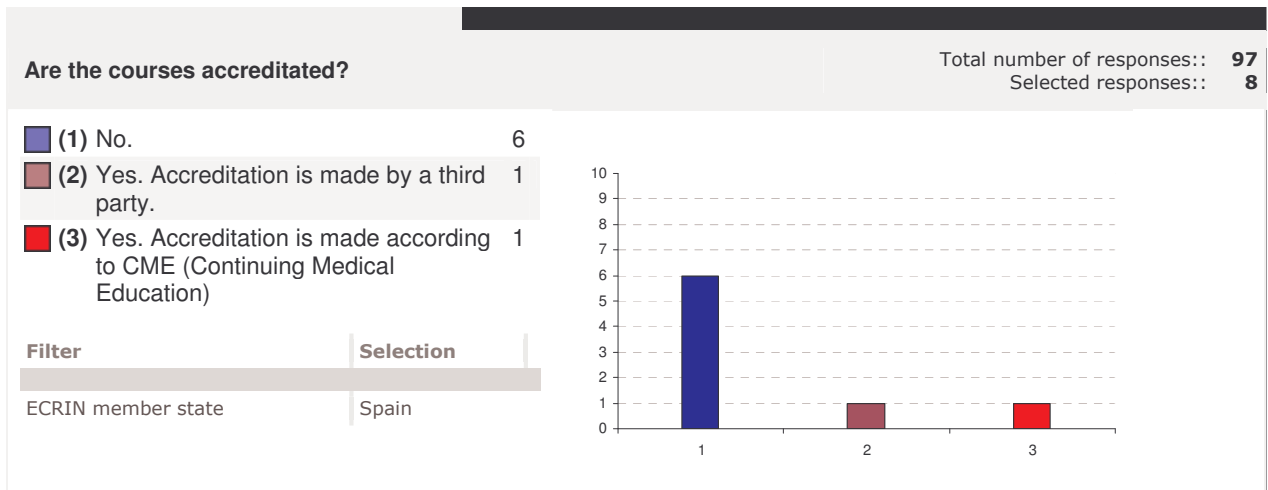
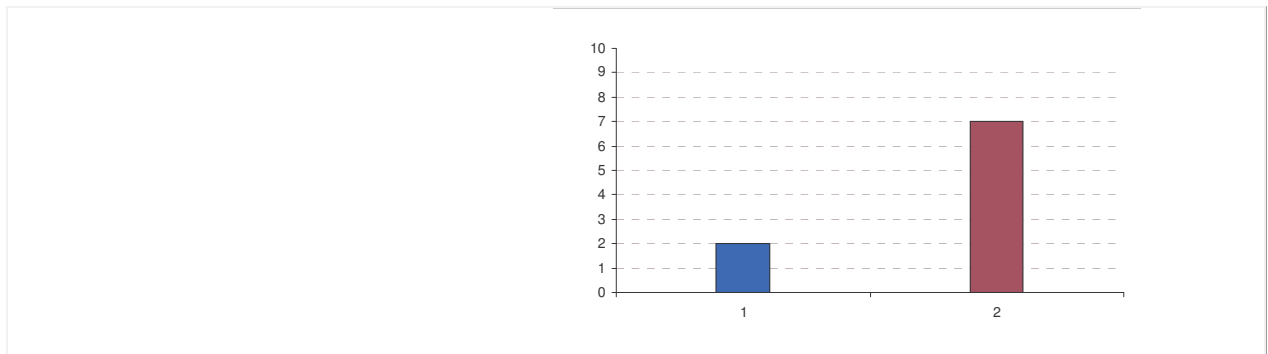
Spain



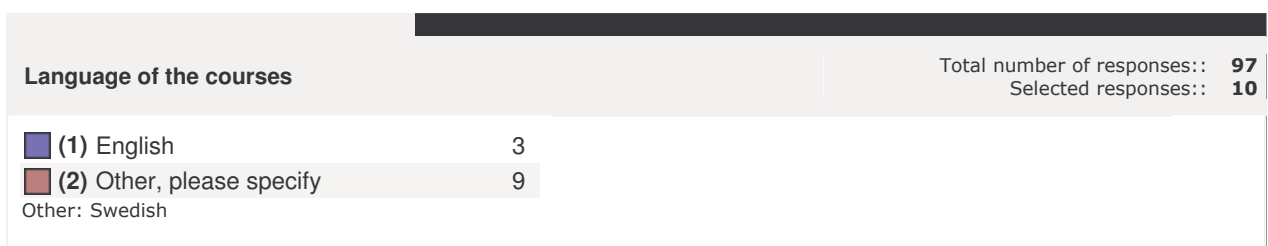
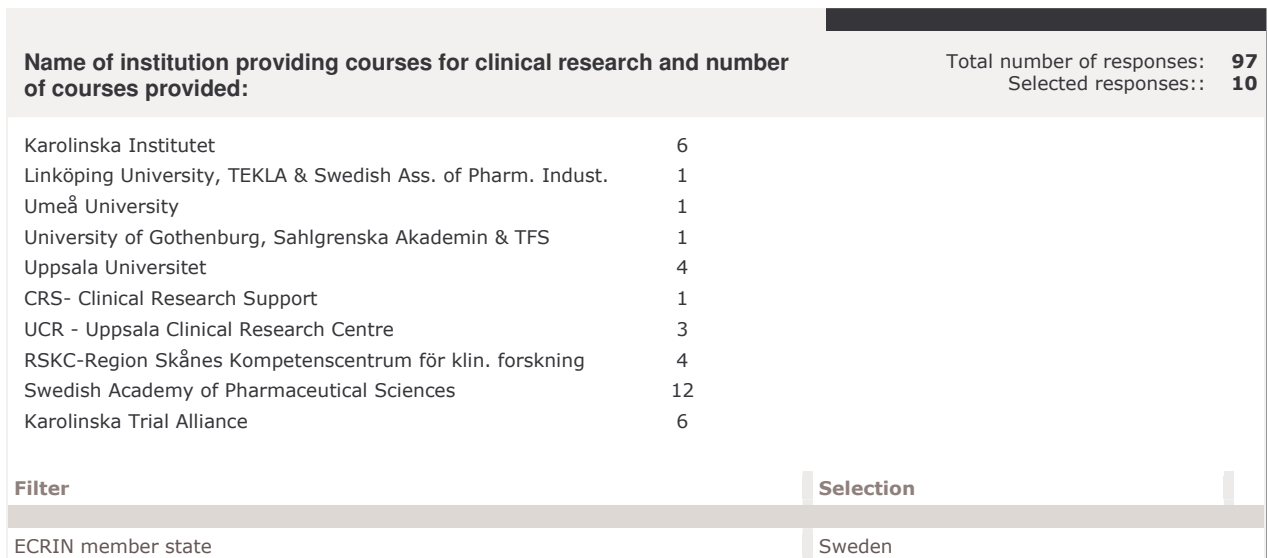


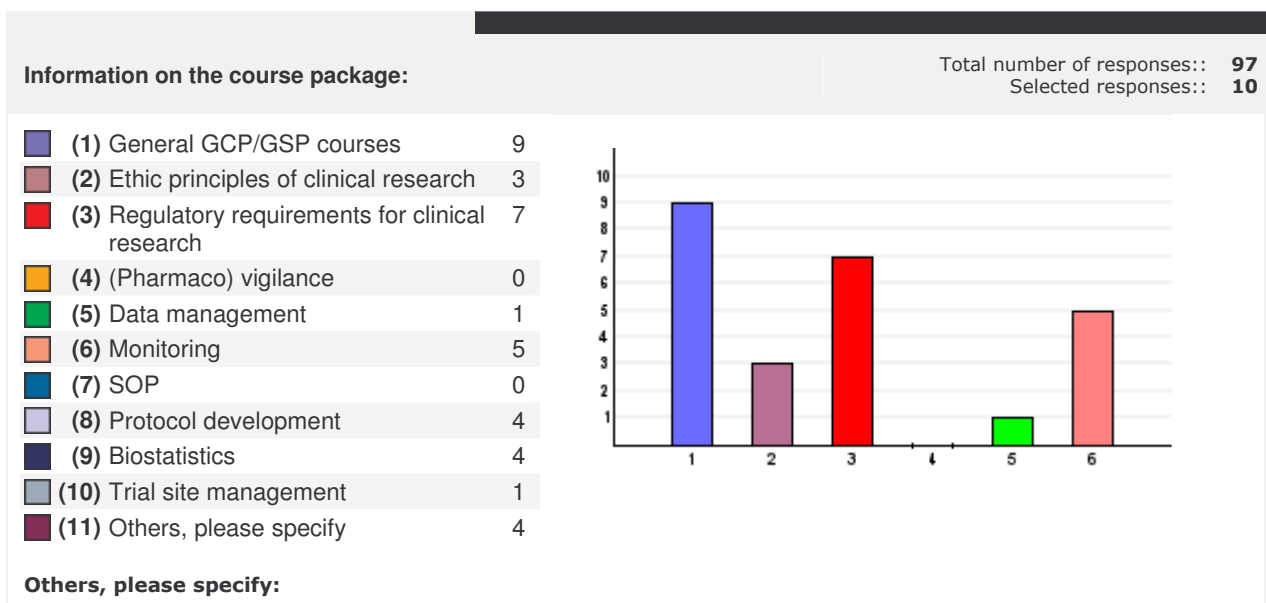
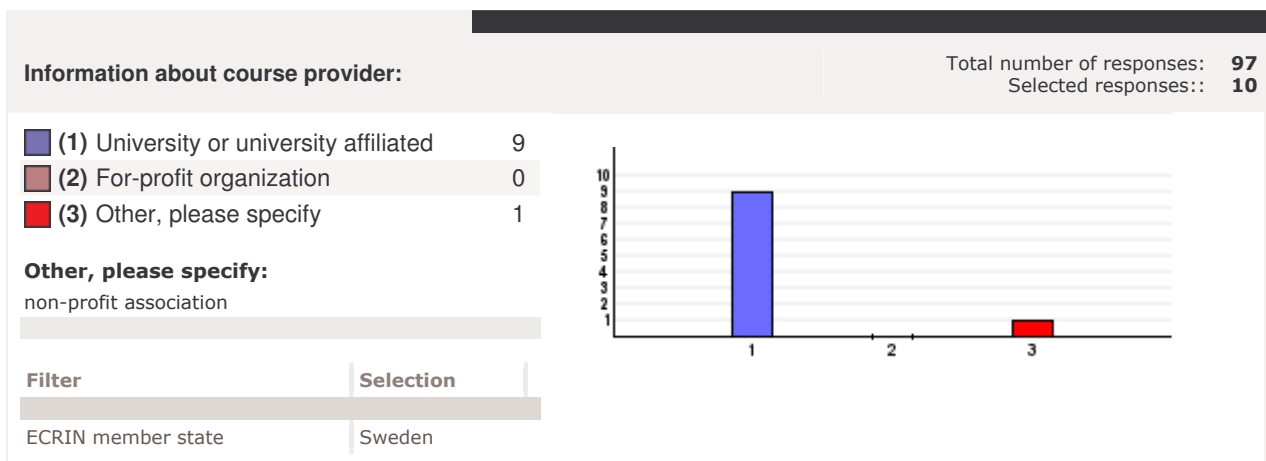
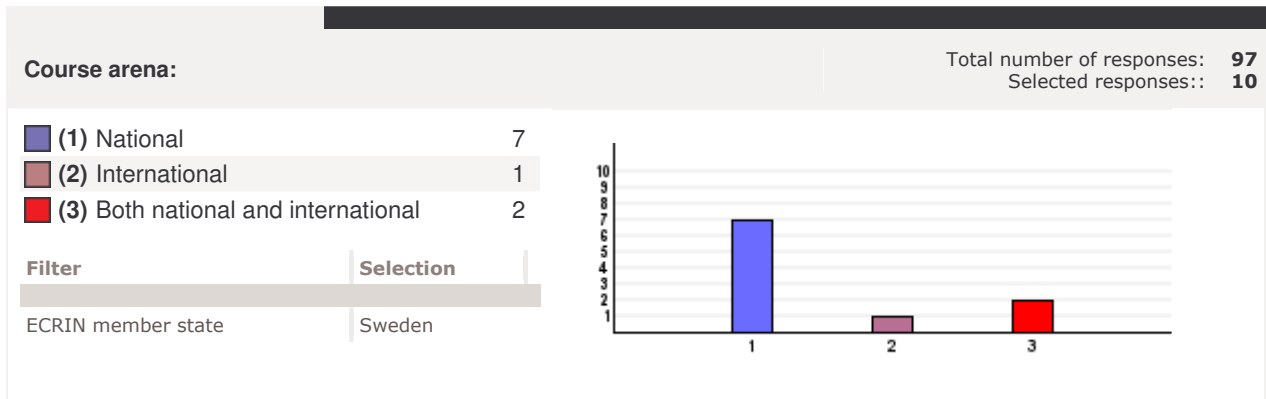
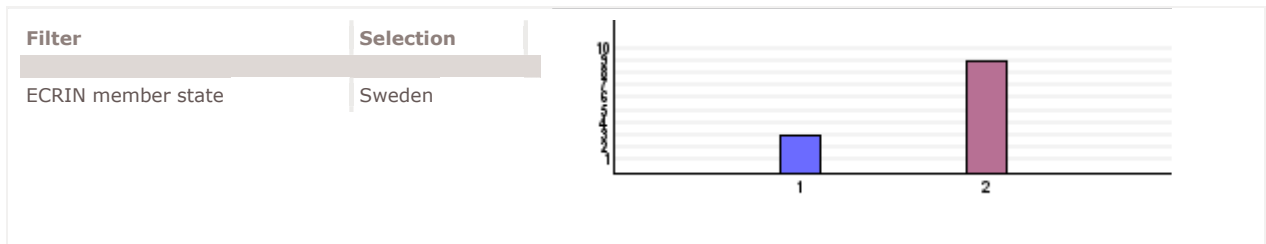
Filter	Selection
ECRIN member state	Spain



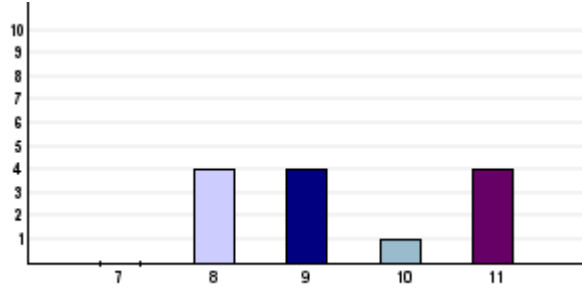


Sweden





Contracting in clinical trials	
Epidemiology, Clinical Trials	
QA, Pharmaceutical Medicine	
Report writing, Medical Device, Project Management	
Filter	Selection
ECRIN member state	Sweden



Type of courses:

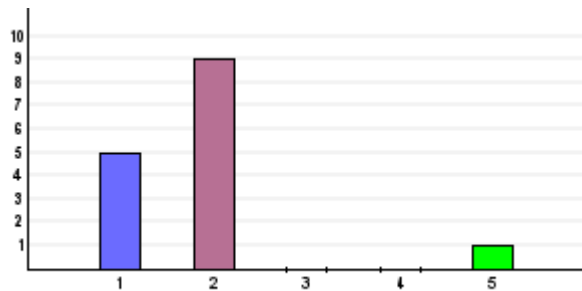
Total number of responses: 97
Selected responses: 10

(1) ETCS points	5
(2) Face to face courses	9
(3) E-learning courses	0
(4) Combination of face to face and e-learning	0
(5) Others, please specify	1

Others, please specify:

3 courses are non ECTS courses

Filter	Selection
ECRIN member state	Sweden



Information about course participants: Who can participate?

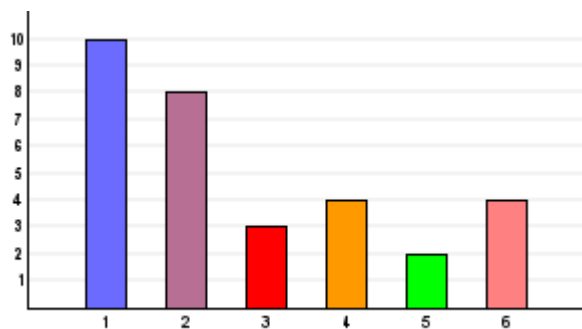
Total number of responses: 97
Selected responses: 10

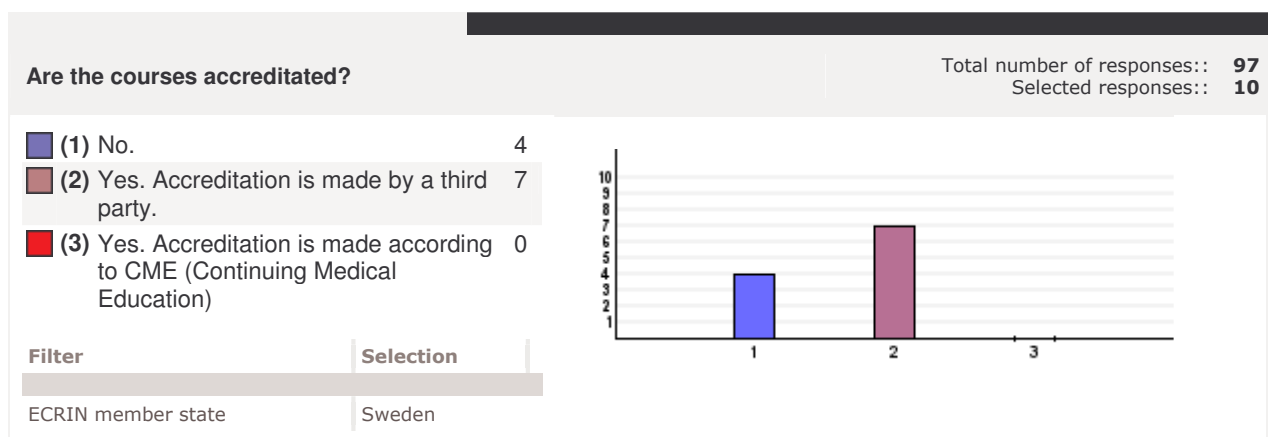
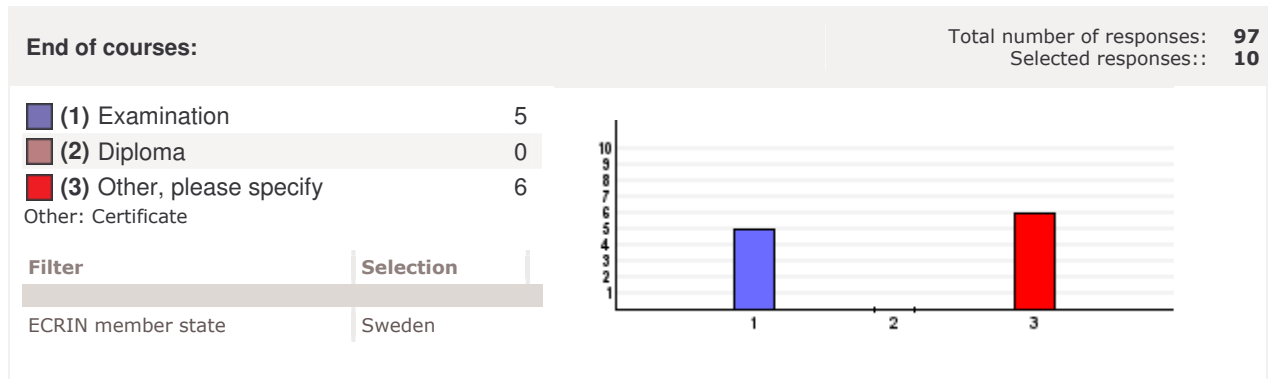
(1) Physician/Investigator	10
(2) Study nurse	8
(3) Biostatistician	3
(4) Monitor/CRA	4
(5) Member of ethics committee	2
(6) Others, please specify	4

Others, please specify:

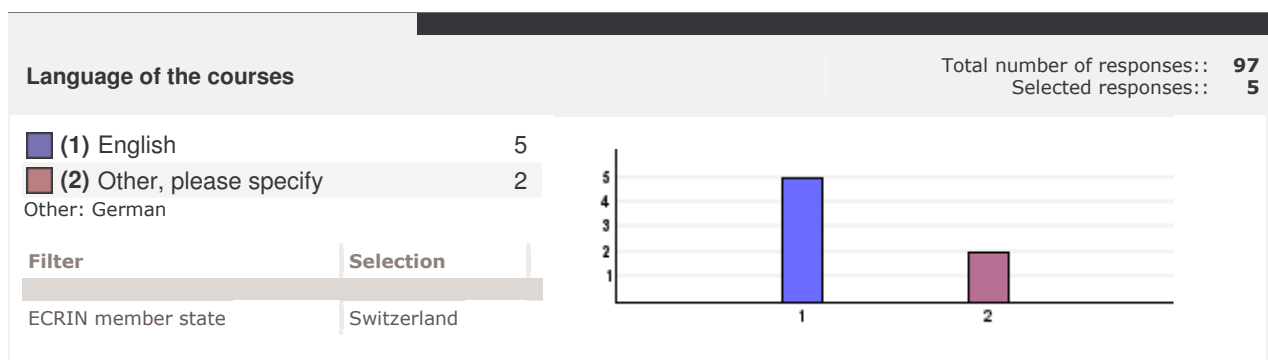
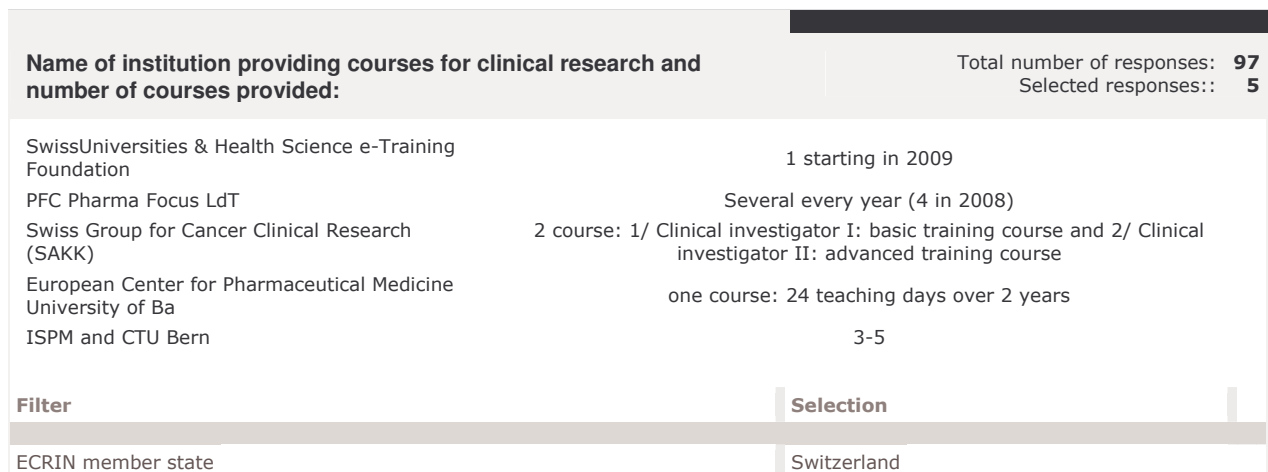
BMA
BMA
industry employee
PhD or Master program students

Filter	Selection
ECRIN member state	Sweden





Switzerland

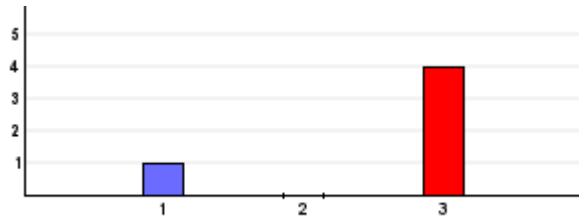


Course arena:

Total number of responses:: **97**
Selected responses:: **5**

- (1) National 1
- (2) International 0
- (3) Both national and international 4

Filter	Selection
ECRIN member state	Switzerland

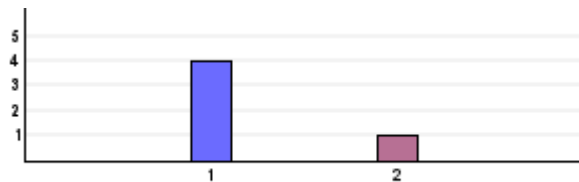


Information about course provider:

Total number of responses: **97**
Selected responses: **5**

- (1) University or university affiliated 4
- (2) For-profit organization 1

Filter	Selection
ECRIN member state	Switzerland

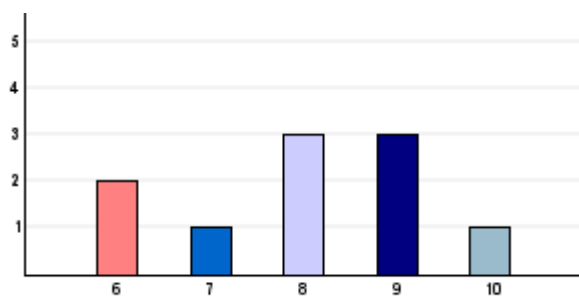
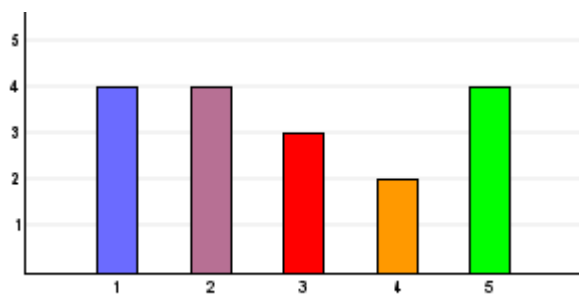


Information on the course package:

Total number of responses: **97**
Selected responses: **5**

- (1) General GCP/GSP courses 4
- (2) Ethic principles of clinical research 4
- (3) Regulatory requirements for clinical research 3
- (4) (Pharmaco) vigilance 2
- (5) Data management 4
- (6) Monitoring 2
- (7) SOP 1
- (8) Protocol development 3
- (9) Biostatistics 3
- (10) Trial site management 1

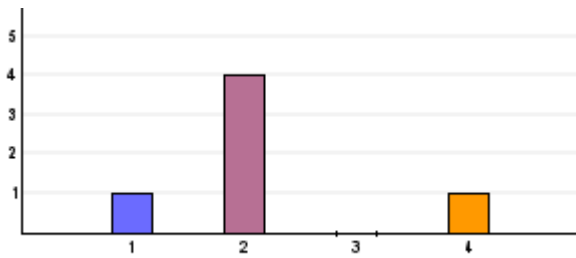
Filter	Selection
ECRIN member state	Switzerland



Type of courses:

Total number of responses: **97**
Selected responses: **5**

<input type="checkbox"/> (1) ETCS points	1
<input type="checkbox"/> (2) Face to face courses	4
<input type="checkbox"/> (3) E-learning courses	0
<input type="checkbox"/> (4) Combination of face to face and e-learning	1

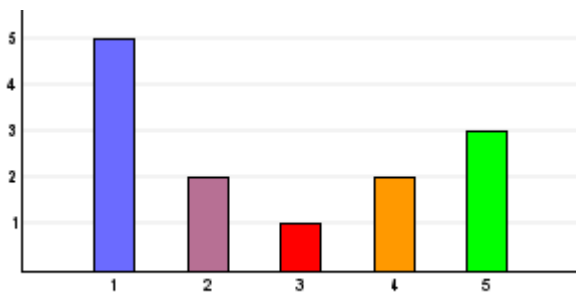


Filter	Selection
ECRIN member state	Switzerland

Information about course participants: Who can participate?

Total number of responses: **97**
Selected responses: **5**

<input type="checkbox"/> (1) Physician/Investigator	5
<input type="checkbox"/> (2) Study nurse	2
<input type="checkbox"/> (3) Biostatistician	1
<input type="checkbox"/> (4) Monitor/CRA	2
<input type="checkbox"/> (5) Member of ethics committee	3

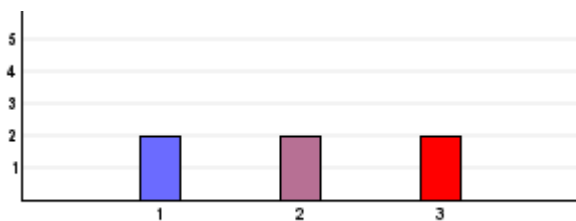


Filter	Selection
ECRIN member state	Switzerland

End of courses:

Total number of responses: **97**
Selected responses: **5**

<input type="checkbox"/> (1) Examination	2
<input type="checkbox"/> (2) Diploma	2
<input type="checkbox"/> (3) Other, please specify	2



Other, please specify:

Confirmation of attendance
no examination, no diploma

Filter	Selection
ECRIN member state	Switzerland

Are the courses accredited?

Total number of responses: **97**
Selected responses: **5**

<input type="checkbox"/> (1) No.	1
<input type="checkbox"/> (2) Yes. Accreditation is made by a third party.	1
<input type="checkbox"/> (3) Yes. Accreditation is made according to CME (Continuing Medical	0

Education)

(4) Yes. Accredited according to the following system (please specify) 3

Yes. Accredited according to the following system (please specify):
 Diploma by the three EUCOR medical schools.
 Swiss Association of Pharmaceutical Medicine
 60 ECTS credits

Filter	Selection
ECRIN member state	Switzerland

Level	Count
1	1
2	1
3	0
4	3

United Kingdom

Name of institution providing courses for clinical research and number of courses provided:

Total number of responses: 97
Selected responses: 1

UKCRN	37
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Filter	Selection
ECRIN member state	United Kingdom

Language of the courses

Total number of responses: 97
Selected responses: 1

(1) English 1

Filter	Selection
ECRIN member state	United Kingdom

Language	Count
1	1

Course arena:

Total number of responses: 97
Selected responses: 1

(1) National 1
 (2) International 0
 (3) Both national and international 0

Filter	Selection
ECRIN member state	United Kingdom

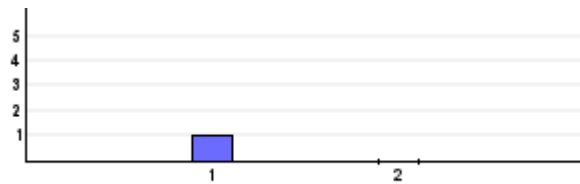
Arena	Count
1	1
2	0
3	0

Information about course provider:

Total number of responses: **97**
Selected responses: **1**

- (1) University or university affiliated 1
- (2) For-profit organization 0

Filter	Selection
ECRIN member state	United Kingdom



Information on the course package:

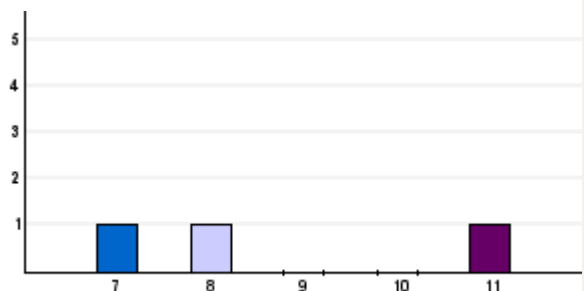
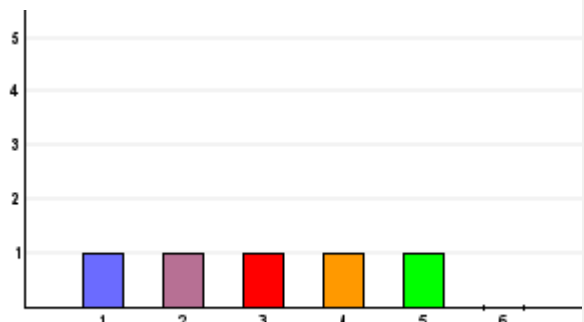
Total number of responses: **97**
Selected responses: **1**

- (1) General GCP/GSP courses 1
- (2) Ethic principles of clinical research 1
- (3) Regulatory requirements for clinical research 1
- (4) (Pharmaco) vigilance 1
- (5) Data management 1
- (6) Monitoring 0
- (7) SOP 1
- (8) Protocol development 1
- (9) Biostatistics 0
- (10) Trial site management 0
- (11) Others, please specify 1

Others, please specify:

MHRA Inspection & Audit, Patient and Public Involvement, Communication Skills for working on Clinical Trials, Working with Industry, Disease specific courses

Filter	Selection
ECRIN member state	United Kingdom



Type of courses:

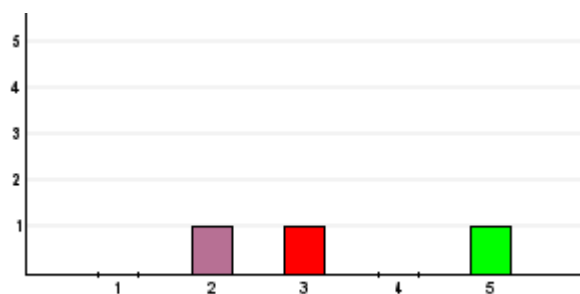
Total number of responses: **97**
Selected responses: **1**

- (1) ETCS points 0
- (2) Face to face courses 1
- (3) E-learning courses 1
- (4) Combination of face to face and e-learning 0
- (5) Others, please specify 1

Others, please specify:

Training video

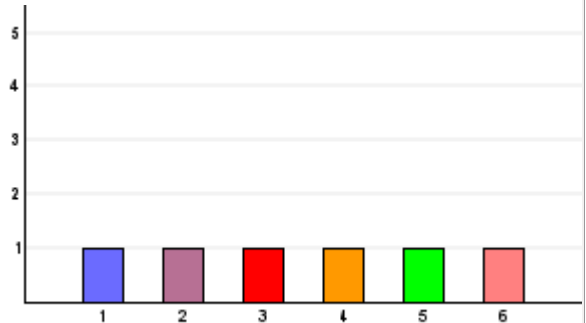
Filter	Selection
ECRIN member state	United Kingdom



Information about course participants: Who can participate?

Total number of responses:: **97**
Selected responses:: **1**

<input type="checkbox"/> (1) Physician/Investigator	1
<input type="checkbox"/> (2) Study nurse	1
<input type="checkbox"/> (3) Biostatistician	1
<input type="checkbox"/> (4) Monitor/CRA	1
<input type="checkbox"/> (5) Member of ethics committee	1
<input type="checkbox"/> (6) Others, please specify	1



Others, please specify:

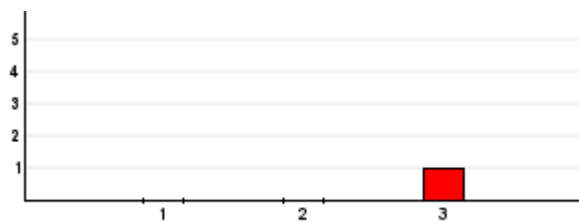
Administrator, Allied Health Professional, Clinical Trial Manager, Data Manager, Information Systems Manager / Officer, Patient Carer, Public Representative, R&D Management, Research Network Manager

Filter	Selection
ECRIN member state	United Kingdom

End of courses:

Total number of responses: **97**
Selected responses: **1**

<input type="checkbox"/> (1) Examination	0
<input type="checkbox"/> (2) Diploma	0
<input type="checkbox"/> (3) Other, please specify	1



Other, please specify:

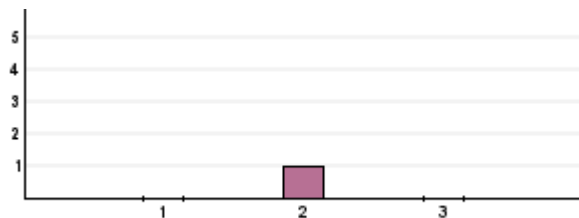
Comprehension tests

Filter	Selection
ECRIN member state	United Kingdom

Are the courses accredited?

Total number of responses: **97**
Selected responses: **1**

<input type="checkbox"/> (1) No.	0
<input type="checkbox"/> (2) Yes. Accreditation is made by a third party.	1
<input type="checkbox"/> (3) Yes. Accreditation is made according to CME (Continuing Medical Education)	0



Filter	Selection
ECRIN member state	United Kingdom

D Discussion

This survey provides a brief overview of the current course package status within the ECRIN member states. Focus is on the organizational level.

Collected data show that almost all countries provide one or many international courses and courses in English. A future interesting aim for ECRIN WP on education and training in ECRIN PPI will be to collect a list of all available international courses.

The course content varies between the ECRIN member states. A few countries (Austria, Finland, France, Germany and Ireland) provide courses covering all the listed course content in the survey and more. The other countries lack one or up to nine courses covering the listed content. Most certainly the information on course content is missing since data from all existing course providers are not present in this survey. Future data entries in the web survey will probably provide a more correct overview.

Five out of twelve ECRIN member states lack ECTS point courses, and four out of twelve does not provide any e-learning courses, according to the collected data.

To incorporate information on ECTS points and e-learning options in the future international course list will be of great importance as this information is relevant for prospective course participants.

All ECRIN member states provide face-to-face courses. This survey does not cover the length of the courses, but it would be of interest to further investigate discrepancies between both course length and course content in the different member states to develop an ECRIN course standard and an ECRIN course certification.

Courses are available for the listed categories of course participants in all ECRIN member states except three. International courses provided by other ECRIN member states could be of great importance for these categories of course participants (biostatistician, Monitor/CRA and Members of ethics committees).

The end of the courses varies between the ECRIN member states. However, most countries have examination and diploma or certificate. A future ECRIN course standard and course certification could help harmonising the end of the courses within ECRIN.

More than 50% of the represented course providers in most countries have accredited courses. This information should also be added to the future international course list.

It is important to stress that the collected data does not cover all existing course providers or courses in each of the represented countries. This is

due both to the limited opening period of the web survey and to the normal changes of upcoming and ending courses within the curriculum of each course provider.

However, the survey is the starting point of a continuously open repository for information about both course providers and courses within the ECRIN member states. The web survey will be developed to contain details of different courses in the next step of ECRIN (PPI).

E Abbreviations

AT	Austria
BMA	Biomedical analyst
CH	Switzerland
CME	Continuing Medical Education
CRA	Clinical Research Associate
DK	Denmark
DE	Germany
ECRIN	European Clinical Research Infrastructure Network
ECRIN-PPI	European Clinical Research Infrastructures Network and Biotherapy Facilities: preparation phase for the infrastructure
ECRIN-RKP	European Clinical Research Infrastructure Network – Reciprocal Knowledge
ECRIN-TWG	European Clinical Research Infrastructures Network-Transnational Working Groups
ECTS	European Credit Transfer System. ECTS is a system of points for the recognition of study performance. 60 points are given per year.
ES	Spain
FI	Finland
FR	France

GCP	Good Clinical Practice
GSP	Good Scientific Practice
HU	Hungary
IE	Ireland
IT	Italy
SOP	Standard Operating Procedures
SE	Sweden
UK	United Kingdom