

SfEE

Attract clinical trials in Greece

February 2021



Executive summary



This project intends to provide an overview of the Clinical Trial's environment in Greece and propose actions for improvement

Project Background

- Clinical trials can be a key driver in the development of science and economy, however Greece is underrepresented in volume and amount of clinical research when compared to comparably sized countries in Europe
- Compared to Greece, Hungary is investing 5 times more, Denmark 30 times more and Belgium is investing 70 times more in pharmaceutical R&D
- SfEE recognizes the significant existing infrastructure in the Greek health care system (high number of hospitals and physicians, favorable tax regime), however it lacks in high volume in clinical research activity
- SfEE has initially identified the focus areas being the hospital engagement (lack of financial incentives) and the patient recruitment and how patient retention can be enhanced

Project Summary

1

Overview of Greece's current clinical trial environment and identification of areas for improvement

2

Recommendations on how to improve the clinical trial environment in Greece based on initiatives implemented by other European countries

3

The value and benefits of Clinical Research in the health sector and the Greek economy

Viewing the current situation of Clinical Trials in Greece, four areas for improvement have been identified

Current situation of Clinical Trials in Greece

- Inadequate awareness of the population
 - Lack of patients' information channels
- Limited specialized hospital staff working on the clinical research field
 - Lack of specialized education of hospital and fiscal agent administrative staff
- Long start-up timelines / long processes in hospitals
 - Negative financial incentive for hospitals to conduct CTs
 - Disruption in the full execution of the CT agreements
- Low R&D spending from Pharmas
 - Lack of modernized, digitalized hospital equipment and IT infrastructure

Identified areas for improvement









Improve patient recruitment

Provide special education to hospital administration and fiscal agents' staff

Simplify administrative framework & processes

Incentivize investments in R&D and digitize infrastructure

The recommendations can be implemented by following the actions already performed in the four European countries examined

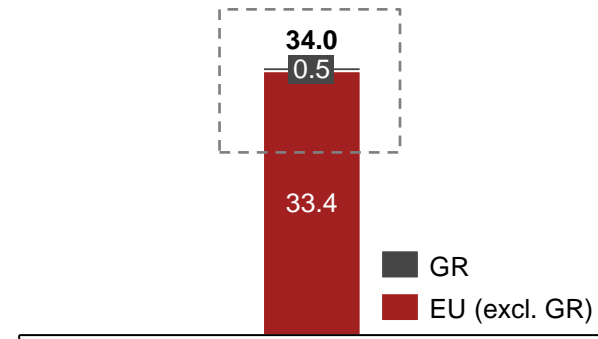
	Main recommendations	Relevant initiatives in Europe	
Patient recruitment	Develop a single access point or portal for access to research information	Establishment of Trial Nation	
	Organize campaigns to promote awareness using channels like Facebook, Google & television	Running the “OK to ask” campaign	
Special education and specialization of staff	Offer learning & development courses to the hospital workforce involved in Clinical Trials in the form of specialized training	Creation of Atrium’s online courses	
	Aim to increase participation in post graduate programs regarding CTs	Participation in ERASMUS+ project (CONSCIOUS)	
Regulatory framework & processes	Connect Leadership performance with KPIs (i.e. time from submission to approval, number of patients participating in clinical trials etc.)	Using metrics to monitor the performance of researchers and sites	
	Organize dedicated CT offices or contact points inside hospitals	Establishment of the National Innovation Office	
Investments & IT infrastructure	Incentivize R&D spending	Establishment of laws that allow high level of commitment among health care stakeholders	
	Strengthen digital infrastructure to deal with the impact of COVID-19	Development of an online hospital database with patient files	

Sources: Sources: trialsjournal.biomedcentral.com, europa.eu, iconplc.com, interregeurope.eu, advarra.com

Interventions in the aforementioned areas can elevate the country's CT state and transform Greece into a Clinical Trial Hub

Indicative scenario

- ~**34.0 bn. €** annual investments in pharma R&D in Europe
- Greek population is ~**1.5%** of the total European population
- If Greece would invest 1.5% of the total European pharmaceutical R&D spending, **0.5 bn. €** would be invested in Clinical Studies



Investments of 0.5 bn. € in pharmaceutical R&D are expected to result in:



1bn € increase in GR GDP



180 mln. € revenues from taxes



23k new job positions

- Creation of variety of high quality job positions (e.g. nurses, doctors)
- Reduction of unemployment



Additional source of hospital funding



Reduction of NHS costs as borne by the Sponsor



Tax contribution

Agenda

Current Situation of Clinical Trials

Recommendations

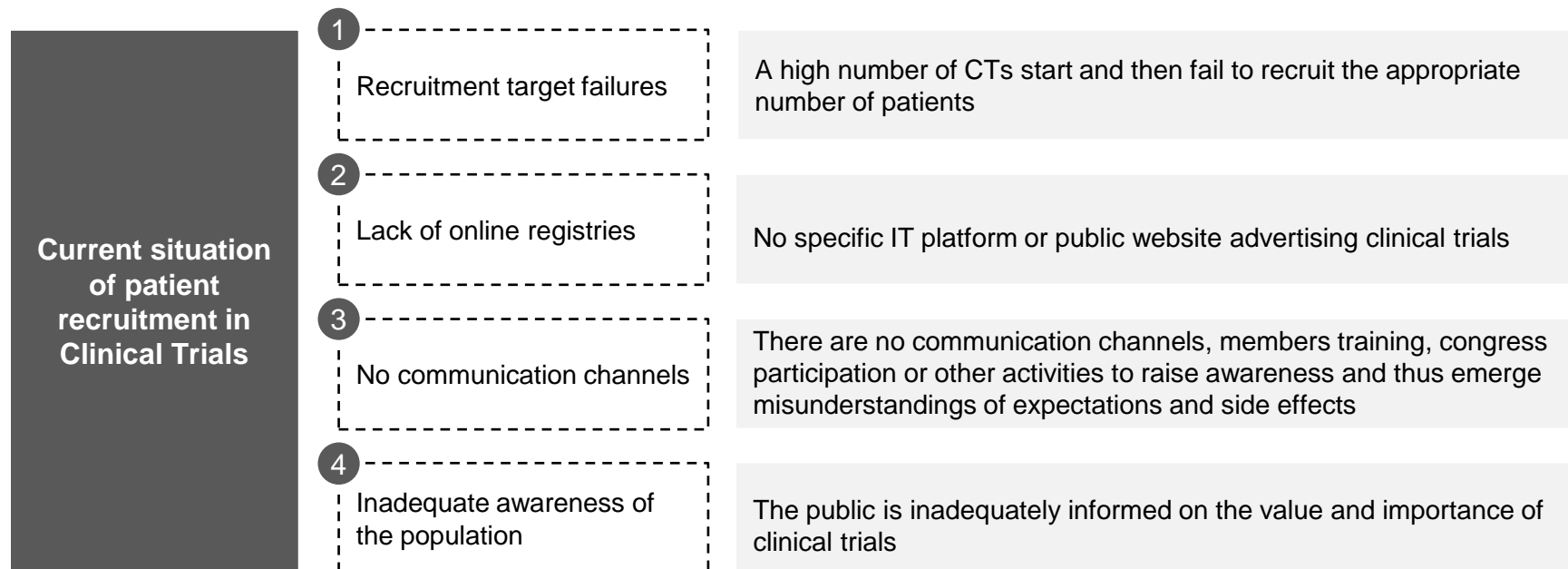
Appendix A: European Best Practices

Appendix B: European Examples

Based on the current situation of Clinical Trials in Greece, four areas for improvement were identified



Major part of CTs is the recruitment of patients; in Greece people's engagement and awareness of the conducted CTs is limited



Knowledge is the most crucial component in the path of successful recruitment in Greece

Clinical Trials and product development have been recently put in the public eye, due to Covid-19. Taking advantage of that, can help promote CTs in all therapeutic areas

Source: Digitalization of Clinical Trials, Client data

There is limited specialized hospital staff and no special education programs are taking place

Limited specialized staff in hospitals

- 1 Limited specialized hospital staff working on pharmaceutical research field
- 2 Lack of specialized education of hospital administrative staff
- 3 Not clear responsibilities amongst involved hospital administrative staff

In a relevant market study focused on hospitals, **44%** of researchers reported the lack of staff exclusively involved with CTs, stressing the need for specialization of staff

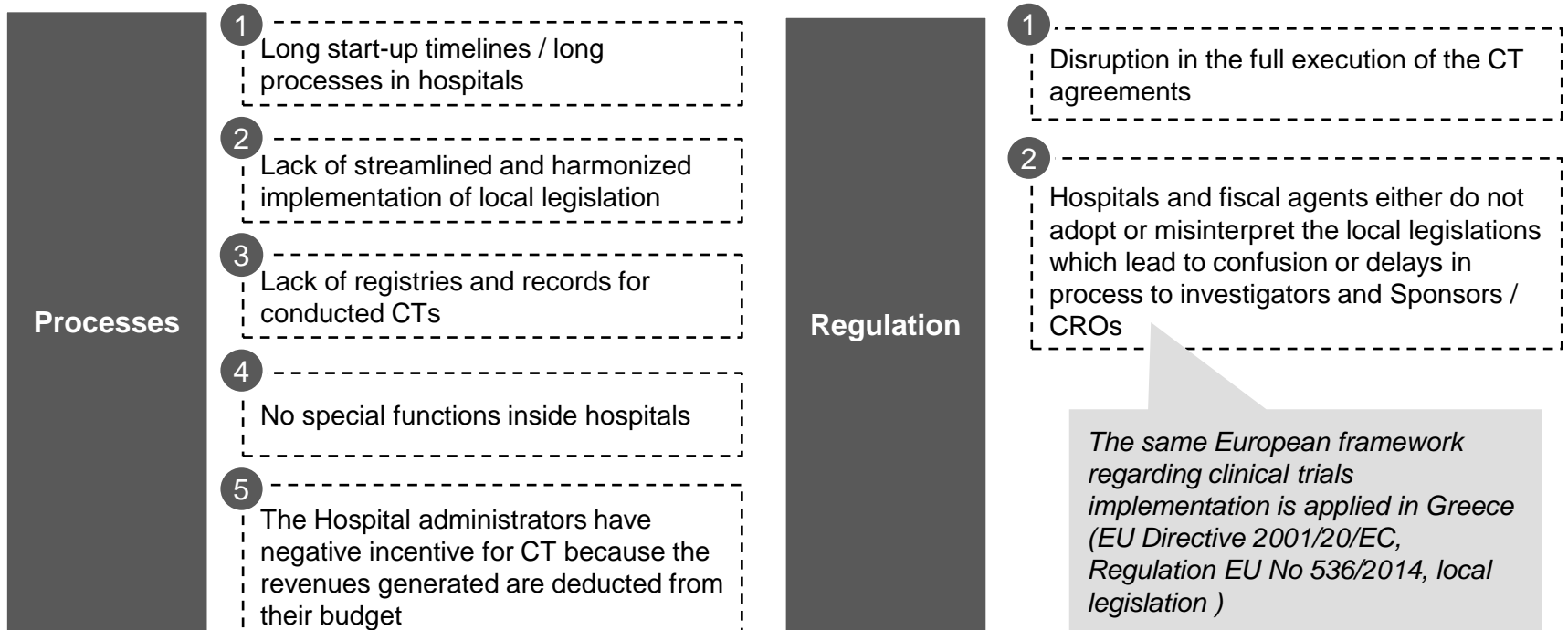
At the same time, lack of education of the relevant administrations results in them not taking initiative to support / conduct CTs



As per OECD “education, training and infrastructure required for academic clinical trials are key elements of the success of clinical research”

Source: medi mark survey

Greek CT environment is suffering from timely processes while international regulatory framework is facing implementation issues



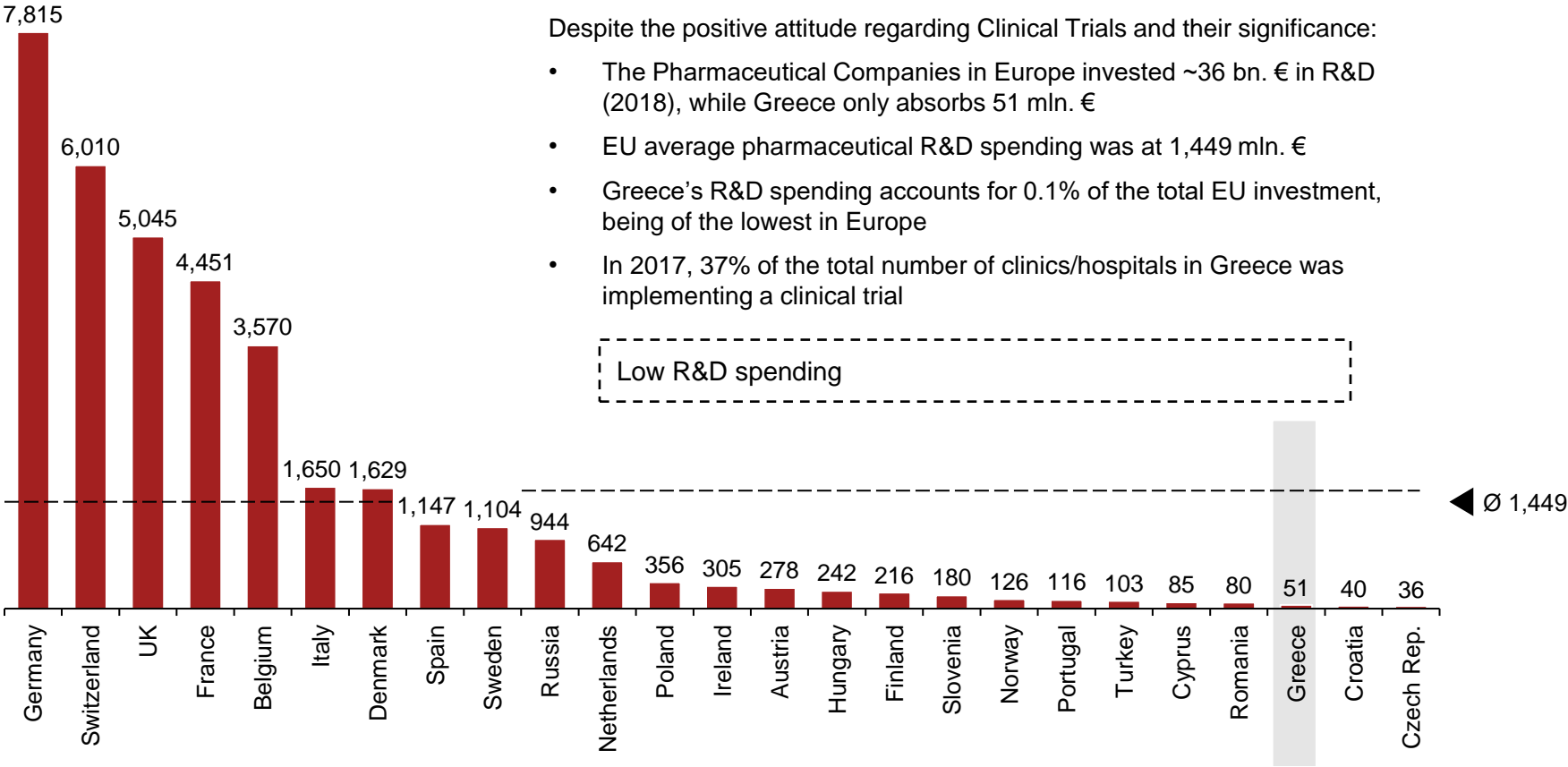
Results of a survey regarding CT's processes and framework that was conducted at hospitals concluded on similar findings:

- 37% of research staff reported bureaucracy and long processes
- 22% of research staff reported there is no special infrastructures inside hospitals (i.e. CT offices)
- 48% of financial staff reports lack of processes and infrastructure for CTs
- 22% of financial staff reported there are no relevant processes to check revenues from trials
- 19% of financial staff reported lack of monitoring systems

Source: medi mark survey

Despite the significance of Clinical Trials, Greece has been lagging behind in the clinical research sector...

Pharmaceutical R&D spending in European countries (2018, mln. €)



Despite the positive attitude regarding Clinical Trials and their significance:

- The Pharmaceutical Companies in Europe invested ~36 bn. € in R&D (2018), while Greece only absorbs 51 mln. €
- EU average pharmaceutical R&D spending was at 1,449 mln. €
- Greece's R&D spending accounts for 0.1% of the total EU investment, being of the lowest in Europe
- In 2017, 37% of the total number of clinics/hospitals in Greece was implementing a clinical trial

Source: The Pharmaceutical Market in Greece

...while at the same time Greece is lacking modernized digitalized hospital equipment and IT infrastructure

Coronavirus crisis has been generating an enormous effort of information systems development and internet exploitation whereas in Greece:

- Obsolete processes and procedures are still in use in Clinical Research
- There is lack of digital archives of patient health data and national integrated hospital platforms
- Despite of statistical e-Governance indicators showing improvement in Greece's IT infrastructures, there is still a lot of room for improvement



Greece is lacking modernized digitalized hospital equipment and IT infrastructure

Source: Using open source technology to virtually implement a patient recruitment system for COVID-19 clinical research and disease monitoring in Greece

Agenda

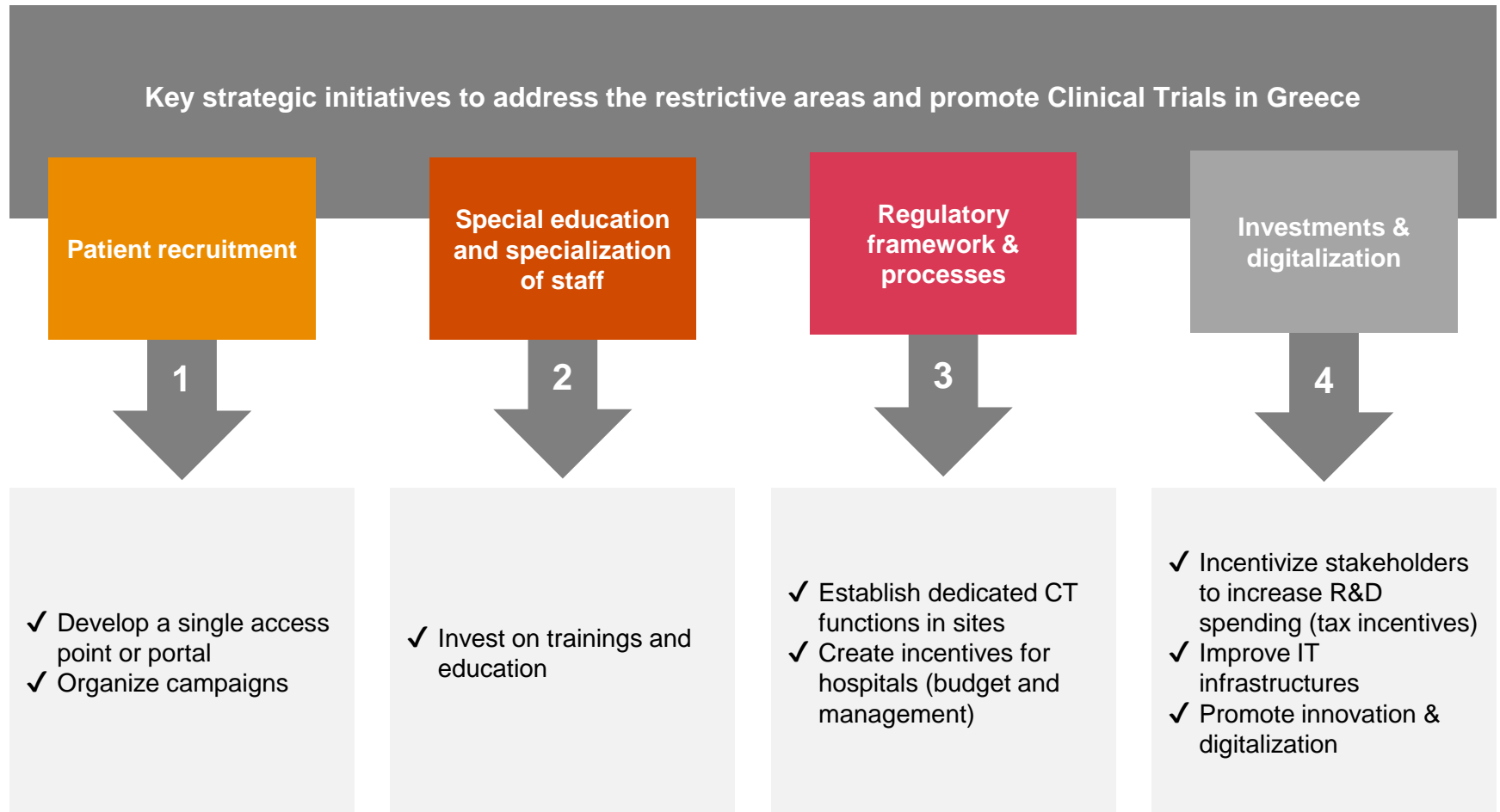
Current Situation of Clinical Trials

Recommendations





Appendix A: European Best Practices

Appendix B: European Examples

Key strategic initiatives in four areas are recommended to the Health Authority for implementation







Focusing on raising awareness & promoting opportunities for access to innovative medicines can improve patient recruitment

Area for improvement	Actions				
Patient recruitment	Develop a public independent information platform for patients concerning clinical trials in Greece - this can also become a tool for initial patient qualification for particular projects		✓		✓
	Improve patients' access to information about potential participation in innovative therapies	✓	✓		✓
	Carry out informational campaigns for patients about Clinical Trials, aiming to raise patient awareness and create a positive environment around asking and getting informed about Clinical Trials	✓	✓		
	Digital recruitment and raising awareness of the public through channels like Facebook, Instagram, and Google and traditional methods, like print and radio	✓	✓		





Source: pharmavoices.com, pubmed.ncbi.nlm.nih.gov, nih.ac.uk

Trainings at CT centers and education of staff, competent authorities and ECs could increase the number of specialized professionals

Area for improvement	Actions				
Special education and specialization of staff	CT centers & their staff				
	<ul style="list-style-type: none"> Aim to increase participation in post graduate programs regarding CTs (e.g. Clinical and Industrial Pharmacology) Invest on PhD students to get involved with Clinical research 	✓			
	Create and standardize trainings		✓	✓	
	Establish an online platform/ network where pharmaceutical research staff can collaborate, discuss and build a network regarding Clinical Research		✓		✓
	Authorities and ECs				
	Offer trainings in relevant multi-disciplinary expertise (ethics, protocol assessment)		✓	✓	





Sources: Clinical Trials in Poland – Key Challenges, docmed.gr, Clinical Research Footprint and Strategic Plan to Promote Clinical Trials in Belgium, Recent developments on clinical trials in Belgium

Development of clear standards, regulations and guidelines could create the foundations for a supportive governmental framework

Area for improvement	Actions				
Regulatory framework & processes	Promote a streamlined and harmonized implementation of local legislation			✓	
	Create a central access point for regulatory questions		✓	✓	
	Promote collaborations between industry, academia and public authorities		✓	✓	
	Organize dedicated CT offices or contact points inside hospitals			✓	
	Establish KPIs/ metrics that will measure hospitals performance on Clinical Trials	✓			

Sources: Clinical Trials in Poland – Key Challenges, docmed.gr, Clinical Research Footprint and Strategic Plan to Promote Clinical Trials in Belgium, Recent developments on clinical trials in Belgium

Setting a favorable environment and development of CT centers could attract pharmaceutical companies and investors

Area for improvement	Actions				
Investments & digitalization	Tax incentives				
	Tax policies can create a favorable environment			✓	
	Stronger branding of the country (e.g. enhance visibility of academic potential)	✓			
	IT Infrastructure				
	<ul style="list-style-type: none"> • Establishment of a digital database with patient data (Electronic health records) • Implementation of the initiative with currently existing patient files (collection of the existing data and integration in a consolidated database) • Introduce AI systems for the process of large amounts of patient data 				✓

Source: Clinical Research Footprint and Strategic Plan to Promote Clinical Trials in Belgium

Agenda

Current Situation of Clinical Trials

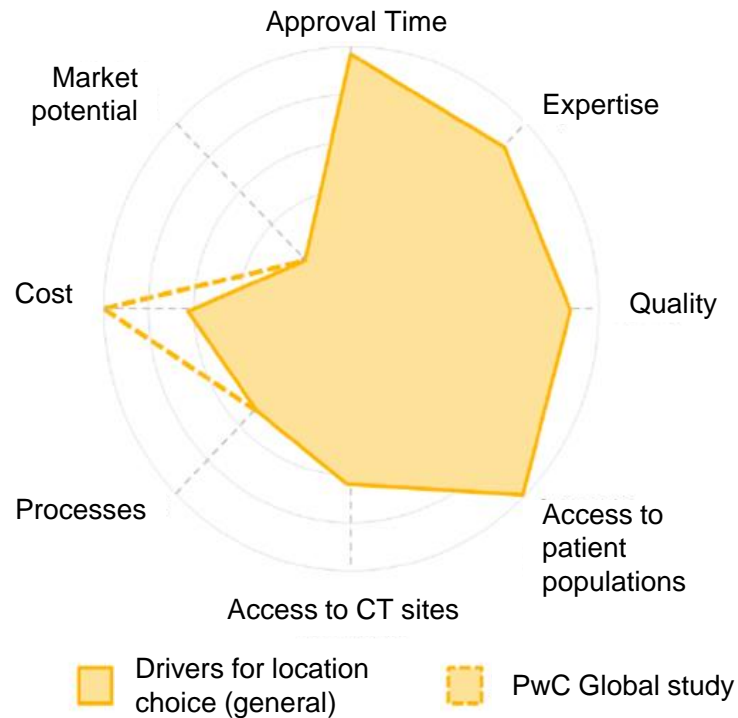
Recommendations

Appendix A: European Best Practices

Appendix B: European Examples

Considering the key drivers for CT location choice...

Most important factors when choosing a CT location



Global Drivers for clinical trial location choice

Decisions on clinical trial location are driven by factors like time, cost, expertise, quality, processes, access to patients, access to trial sites and market potential:

- **Time, cost and access** to patients are key drivers for clinical trial location choice
- **Quality and expertise** also greatly impact location choice
- **Approval process and access to clinical trial sites** are relatively less important drivers
- **Market potential** is comparatively the least important driver of location choice

...four countries, which have created an attractive environment by implementing strategic initiatives, were selected as benchmarks

- Four European countries that have implemented transformations in their CT environment were selected
- The Best Practices and current state of these countries were identified



United Kingdom



Denmark

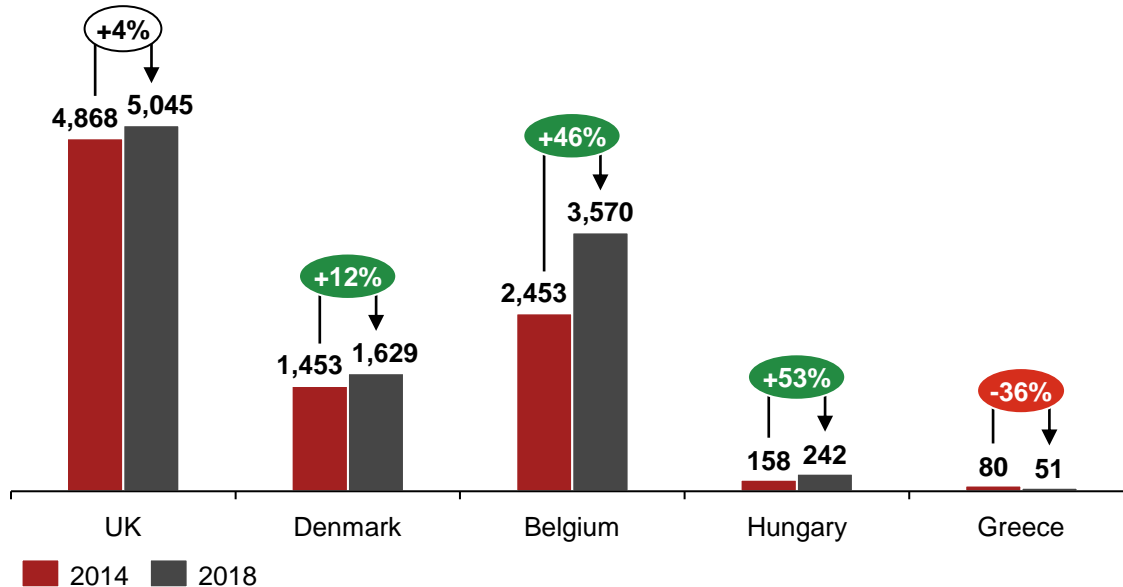


Belgium



Hungary

Pharmaceutical R&D spending (2014 vs 2018, mln. €)



Source: EFPIA

- The UK is one of the countries with the highest pharma spending in Europe and has managed to further increase investments since 2014
- Belgium and Hungary have both managed to almost double pharmaceutical investments in the period 2014-2018
- Greece's pharmaceutical R&D spending is one of the lowest in Europe and has further declined by 36% (30 mln. €) since 2014



Promotion of CTs in the UK has raised awareness in the general population regarding clinical research...

Initiatives

Establishment of an agency for the development and promotion of clinical trials supporting the development of clinical trials, particularly those of transnational importance

The agency carries out informational campaigns for patients about clinical trials, which aim at raising patient awareness and developing positive conditions for asking about taking part in clinical trial ("OK to ask" campaign in the UK)



Results

- High rate of patient recruitment
- Greater motivation for patients to become involved in clinical trials, compared to mature Western European markets
- Access to patients of specific therapeutic areas

Establishment of the National Institute for Health Research (NIHR)



The NIHR Patient Engagement in Clinical Development Service connects life science companies with patients who want to help shape and improve the design and, ultimately, the delivery of commercial clinical research

Promoting public awareness of randomized clinical trials using the media ('Get Randomized' campaign in Scotland)



- Television, radio and newspaper advertising showed leading clinical researchers, general practitioners and patients informing the public about the importance of randomized clinical trials (RCTs)

In the "Get Randomized" campaign in Scotland, 56.7% of the sample recalled seeing or hearing advertisements about CTs, compared to 14.8%, prior to the campaign



... and along with monitoring performance using metrics, it has been achieved a more effective conduction of CTs

Initiatives

Connect Leadership performance with KPIs, such as:

- time from submission to approval
- proportion of final databases locked on time
- proportion of studies completing
- patient enrollment on time
- trial retention percentage
- proportion of vendors with critical findings following an audit



Results

- KPIs, linked to strategic aims, measure the impact of management performance, provide assurance to stakeholders, drive continuous improvement; operational KPIs and reporting enable effective performance management
- Using metrics has provided performance information to researchers and the wider research community



International studies have shown **KPIs** have multiple benefits:

For internal operations:

- Identification of possible areas for improvement
- Identification of possible changes in resource allocation
- Achieving of more effective workload management between teams
- Establishment of performance benchmarks
- Communication with leadership for providing rationale and receiving resources

For determining relationships with sponsor:

- Identification of areas of strong competitive advantages
- Identification of possibilities to complete site feasibility questionnaires with real data

Sources: hra.nhs.uk, advarra.com



Denmark has implemented innovative solutions, like encouraging continuous training, establishing the NEXT...

Initiatives

The Danish Association of the Pharmaceutical Industry has partnered with Atrium for the creation of a website that offers a series of courses on clinical research



Results

- Development of an online platform, where clinical research staff (students, doctors, researchers) can attend trainings and expand their skills and knowledge

Establishment of the National Experimental Therapeutic Partnership (NEXT) which is a public-private partnership. NEXT network of disease-specific research centers is placed at Danish university hospitals to conduct trials



Brought together industry, leading clinicians, regulatory agencies, ministries and patient organizations. The benefits are addressed to:

- **Patients:** Access to new medical treatment and possibility of personalized patient treatment, involvement in drug development processes
- **Industry:** Easy access to excellent research environments in Denmark, fast clinical trials, access to unique health data, closer public-private collaboration
- **Healthcare System:** Experiences with new medical treatments, education of staff, increased possibilities for patient treatment, continuous optimization of clinical trial processes and procedures

Sources: healthcaredenmark.dk, danishpaintrialcenter.com, investindk.com, atriumcph.com



...and also establishing a national Clinical Trial website (TrialNation), a one-stop shop for enabling access to and conduction of CTs

Initiatives

Establishment of TrialNation (one-stop shop)



Results

- Development of a single, national entry point where company owners, investors, patients and clinical researchers can get information about sponsoring, participating in and conducting clinical trials in Denmark
- In detail, Trial Nation offers:
 - Identification of relevant specialists and clinical researchers.
 - An expedited feasibility process with a collated, national response from hospital sites within five days
 - Access to our legal network, offering legal advice and national contract negotiation
 - Access to established clinical specialty centers and national networks within different health sectors
 - A national approach to increasing performance in clinical trials
 - Access to established partnerships with hospitals, scientists and patient networks

Since 2018, when Trial Nation was established, the number of CTs increased by 2.6 times

Sources: healthcaredenmark.dk, danishpaintrialcenter.com, investindk.com

In Belgium, establishment of FAMHP and signing the “Pact of the Future” have stimulated growth and innovation...

Initiatives

Establishment of FAMPH and the National Innovation Office within the FAMPH organisation, a specifically designed access point for regulatory questions regarding Clinical Trials



Signing of the ‘Pact of the Future’ with the pharmaceutical sector, in an effort to create a stable framework for investors in pharmaceutical R&D



Results

- Belgium has an one-stop shop for all relevant staff involved with CTs; through the National Innovation Office, companies and researchers are encouraged to set up early-phase CTs and SMEs are supported in their R&D activities
- Creates a stable, predictable and reliable budgetary framework within which Pharmas can better plan their research and development on new drugs. A central contact point established to provide regulatory support to spin-offs and start-ups
- Monitors the competitive position of the Belgian Pharma market on a permanent basis
- It is a unique package of agreements and stresses a **sustainable patient-oriented drug policy, cheaper drugs, and faster reimbursement procedures** (shortening the procedure by more than 50 days). This means that new products can come onto the market faster and, at the same time, it provides scope to finance important new innovation.

*As a direct result of the favorable economic climate, **2 major pharmaceutical investments were welcomed in Belgium: JLINX by J&J and a Genzyme R&D facility by Sanofi***

Source: eccrt.com, Clinical Research Footprint and Strategic Plan to Promote Clinical Trials in Belgium, Recent developments on clinical trials in Belgium, Belgium, a European leader in clinical trials



...while Tax policy also privileges innovators and investors with training to remain another factor of success

Initiatives

Effective Corporate tax rate which is lower than that of other EU countries (Netherlands, Germany, France)



Results

- Patent income deduction
- 80% payroll withholding tax exemption for scientific researchers
- Refundable R&D tax credit system
- National interest deduction (new, innovative and powerful measure in international tax law)

Establishment of the European Centre for Clinical Research Training (ECCRT), a professional clinical research training provider



- Offering of technical (regulatory, clinical operations, quality assurance etc.) trainings
- Management, leadership, communication learning for involved staff
- Transferring of knowledge in the day-to-day activities of the participants

Source: eccrt.com, Clinical Research Footprint and Strategic Plan to Promote Clinical Trials in Belgium, Recent developments on clinical trials in Belgium, Belgium, a European leader in clinical trials, mediplanet.be, mondaq.com

Hungary has achieved to maintain its clinical research reputation by creating an attractive local environment

Initiatives

- Centralized health care system
- Rapid patient recruitment



Results

- 18 out of 160 governmental hospitals are specialized in conducting phase I studies
- The majority of the private hospitals are engaged in clinical trials, utilizing site management organization (SMO)
- Patient populations show a high degree of trust and are willing to get access to advanced treatments

Innovative and well-organized infrastructure for clinical trials – access to patients, good quality sites, all supported by authorities



- In 2018, they involved Hungarian patients in clinical trials across 150 sites
- They conducted 82 research studies across 6 therapeutic areas
- They generated a cost savings of USD 20.5million for the Hungarian drug budget

- *Hungary is placed 10th in terms of the number of trials and 4th in terms of accessibility and availability of trials per capita (within Europe)*
- *Roche has selected Hungary as their strategic destination for clinical activity*
- *Hungary has established OGYEI, the methodical and research institute of Hungary*

Sources: pharmaboardroom.com, swanmed.eu

Agenda

Current Situation of Clinical Trials

Recommendations

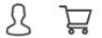
Appendix A: European Best Practices

Appendix B: European Examples

Denmark's atrium website with online courses



Search for courses & programmes



Courses Disciplines About us News Life Science House

atrium

- Courses
- Exams
- Programmes
- Networks
- Seminars
- Events

COURSE CATEGORIES

- Clinical development
- events
- General
- Market access
- Marketing compliance
- Pharma Business
- Pharma consultant

ADVERSE DRUG REACTIONS BY BODY SYSTEMS

Module 7
Read more

Currently available on:
15. Mar 2021

AGILE FUNDAMENTALS AND THE SCRUM FRAMEWORK

Would you like to learn what 'agile' really is and how to use it in your professional role?
Read more

Currently available on:
28. Apr 2021
10. Nov 2021

ANATOMY AND PHYSIOLOGY

Learn about the human body and its physiological functions
Read more

Currently available on:
10. Mar 2021
7. Sep 2021

Trial Nation, Denmark's one stop shop for Clinical Trials



Trial Nation offers a single, national entry point for life science companies, patient organisations and clinical researchers wishing to sponsor, participate in, and conduct clinical trials in Denmark.

Services and resources below:

[Investigator identification >](#)

[Feasibility process >](#)

[National centers >](#)

[Legal >](#)

[Infrastructure >](#)

[Detailed overview of research strategies and research units >](#)

National centers

The infrastructure of Trial Nation is unique: seven national centers ensure easy access to leading hospital departments. The national collaboration ensures a uniform, high quality execution of clinical studies across all participating research units. Trial Nation can initiate and coordinate contact to the relevant center, its associated departments and their contact person.

For more information about the centers, please click on the dropdown below:

- [Dementia >](#)
- [Dermatology >](#)
- [Haematology >](#)
- [Infectious Disease and Immune Modulation >](#)
- [Medtech \(all therapeutic areas\) >](#)
- [Oncology >](#)
- [Other therapeutic areas >](#)
- [Pediatrics >](#)
- [Respiratory >](#)

Legal

The healthcare regions in Denmark have formed a legal network to ensure that the regions act as a united negotiation party in relation to the industry. The network is accessible via Trial Nation.

The network provides efficient negotiation of contracts relating to clinical trials in Denmark. Contract templates can be used as they are or be tailored to your company. Consider using the Danish Regions' standard templates for the fastest possible processing time.

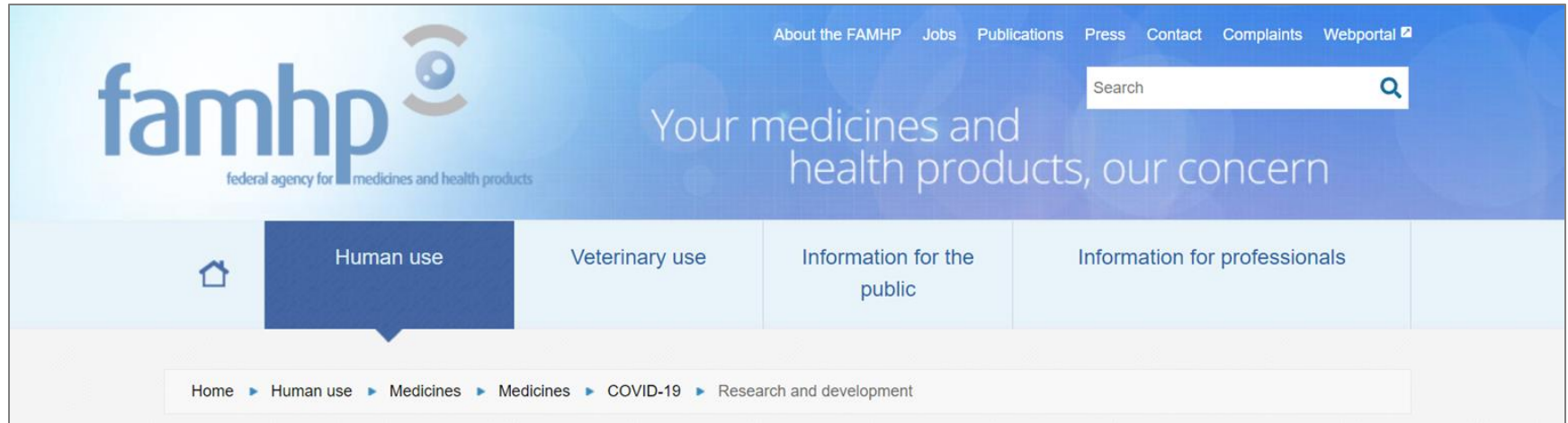
Confidentiality Undertaking for a Clinical trial

Standard Clinical Trial Agreement

Standard Clinical Investigation Agreement – Medical Devices – Please note that this template is currently undergoing review.

You can reach us at legal@trialnation.dk

Belgium's Famhp, where the requests for clinical trials for medicines and health products are evaluated and approved



Our mission in its legal context*

The FAMHP ensures, **from development to use**, the quality, safety and efficacy of medicines for human and veterinary use (including homeopathic medicines, herbal medicines, pharmacy made and official preparations) and also medical devices and accessories, and raw materials for the preparation and production of medicines.

From collection to use, the FAMHP ensures the quality, safety and efficacy of all the operations involving with blood, cells and tissues.

*The law of 20.07.2006 concerning the establishment and functioning FAMHP

Belgium's ECCRT trainings (1/3)



Course Schedule 2021



Classroom Trainings

Due to the COVID-19 situation, almost all our **classroom trainings** from January to March 2021 are scheduled as **webinars** - see green colour



For the full course descriptions and the latest updates, visit our website:

<https://eccrt.com/>

Course Name	Location	Jan	Feb	Mar	Apr	May	Jun	Jul	Sep	Oct	Nov	Dec
QA Related Courses												
A risk-based approach to Clinical Audits	Brussels						16					
Audit and Inspection Readiness - How to be prepared!	Brussels						18					
Auditing Clinical Development Documents	Brussels						17					
Clinical Service Provider Audits	Brussels						17					
Communication and Appreciative Auditing	Brussels						17					
Introduction to System Audits for Clinical Auditors	Brussels						15					
Introductory Course on Auditing Investigator Sites	Brussels						15-16					
Writing Audit Reports	Brussels						14					
Regulatory Courses												
Basics on Regulatory Requirements in Clinical Research	Brussels			08				06				
	Leiden											06
Clinical Research Training for Clinical Trial Assistants (CTAs) <i>(Webinar training sessions available)</i>	Brussels		26, 27, 28, 02, 03				17-18					
Medical Device Regulations	Brussels								27			
Management Courses												
Advanced Clinical Project Management <i>(Webinar training sessions available)</i>	Brussels		22, 23, 26, 01, 03, 05							11-12		
Clinical Project Management <i>(Webinar training sessions available)</i>	Brussels			02, 03, 09, 10			28-29				15-16	
	Leiden								13			
CRO Management and Oversight	Brussels									13-14		
Risk Management in Clinical Research - Blended	Brussels							07			17	
Leadership Courses												
Line Management Essentials	Brussels								23-24			
People Management	Brussels							09			19	
Communication Courses												
Communication Skills	Brussels			12					10			
	Leiden											10
Enhancing your Communication and Presentation Skills in the changing Clinical Trial world	Brussels									14		

Belgium's ECCRT trainings (2/3)

Course Schedule 2021



Classroom Trainings

Due to the COVID-19 situation, almost all our **classroom trainings** from January to March 2021 are scheduled as **webinars** - see green colour



Course Name	Location	Jan	Feb	Mar	Apr	May	Jun	Jul	Sep	Oct	Nov	Dec
SMART SOLUTIONS												
Advanced Auditors STAR Programme	Brussels						14-18					
Advanced CRA STAR Programme	Brussels									11-14		
Advanced Project Management STAR Programme	Brussels									11-15		
Clinical Project Management STAR Programme	Brussels							05-09			15-19	
Junior Auditors STAR Programme	Brussels						14-18					
Junior Clinical Researcher STAR Programme	Brussels			08-12				05-09	06-10			
	Leiden											06-10
Medical Devices STAR Programme	Brussels			15-18								

For the full course descriptions and the latest updates, visit our website:

<https://eccrt.com/>

Other courses available:

Many other training courses are available but aren't scheduled yet. Upon your request we can ensure that you are registered in our waiting list. Otherwise you can also ask for a tailored course for your own organisation (face-to-face or on-line training). Contact us at info@eccrt.com.

- Change Management
- Communicating with EU Regulators/Health Authorities: An Overview of Approach, Planning and Procedure – Webinar
- Effective Medical Writing & Data Presentation
- European Legislation for Clinical Research – Implementation in Belgium
- Female Leadership in Clinical Research
- GMP Essentials for Clinical Operations Staff
- Importance of the Involvement of Clinical Operations in Clinical Study Protocol Review
- Influencing skills
- Intercultural Communication Skills
- Laboratory Testing in Clinical Research
- Leading in a Solution Focused Way
- Liability & Insurance in Clinical Trials in Belgium and Europe
- Microsoft Project Basics for Clinical Project Managers – Series of Webinars
- Paediatric Clinical Development
- Remote Monitoring and Future Opportunities during COVID-19 and Beyond – Webinar
- The ECG in Clinical Research
- Time Management
- Train the Trainer

Belgium's ECCRT trainings (3/3)

Course Schedule 2021



Online: Webinars & eLearnings

For the full course descriptions and the latest updates, visit our website: <https://eccrt.com/>

Course Name	Type	Jan	Feb	Mar	Apr	May	Jun	Jul	Sep	Oct	Nov	Dec
Good Clinical Practice (ICH-GCP E6) Courses												
Foundational ICH-Good Clinical Practice (GCP) E6 (R2) Training	eLearning											
NEW GCP Essentials in 90 Minutes	eLearning											
ICH-GCP E6 (R2) Refresher	eLearning											
ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Biometrics Staff*	eLearning											
ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Clinical Operations Staff*	eLearning											
ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Regulatory Staff*	eLearning											
ICH-Good Clinical Practice (GCP) E6 (R2) Addendum 2016*	eLearning											
ICH-Good Clinical Practice (GCP) E6 (R2) for Investigators	eLearning											
Clinical Operations Courses												
Introduction to Clinical Research	eLearning											
Introduction to Clinical Research with Medical Devices	eLearning											
Investigator Initiated Studies	Webinar				19							
NEW What's new with ISO GCP (ISO 14155)?	Webinar			29								
Clinical Research Related Courses												
Implementing GDPR in your organisation	eLearning											
QA Related Courses												
NEW Inspection Readiness for CRAs and Project Managers	Webinar									15		
Regulatory Courses												
NEW Are you ready for the IVDR? Regulatory impact and milestones for CE marking	Webinar					05						
Clinical Trial Requirements: Comparing Europe with the USA	eLearning											
Good Manufacturing Practice (GMP) in relation to GCP	eLearning											
Local Clinical Trial Legislation in Europe	eLearning	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Norway, Poland, Russia, Spain, Sweden, The Netherlands and UK										
The European Clinical Trial Directive for Medicinal Products	eLearning											
SMART SOLUTIONS												
Regulatory STAR Programme	eLearning											
Career Launch Coaching (flexible schedule)	Webinar											
Clinical Career Coaching (flexible schedule)	Webinar											

T
Technical

Hungary's OGYÉI website, the methodical and research institute of Hungary



H-1051 Budapest, Zrínyi u. 3.
Tel.: (1) 8869-300, E-mail: ogyei@ogyei.gov.hu
Mail: 1372 P.O. Box: 450.



Publications Events Projects

News

OGYÉI issued a temporary authorization for distribution of the product for emergency use

[more](#)

Information on nitrosamines for marketing authorisation holders

[more](#)

Guidance for the MAHs on the preparation and dissemination of DHPCs has been updated

[more](#)



ABOUT OGYÉI

[About us](#)
[Contacts](#)
[Publications](#)



SPECIALIZATIONS

[Medicines](#)
[Pharmacies](#)
[Medical devices](#)
[Health Technology Assessment](#)
[Gene technology](#)
[Electronic Cigarettes](#)



INFORMATION

[Counterfeit medicines](#)
[Individual medicine import](#)
[Travelling with Controlled Drugs](#)
[Nitrosamine contamination](#)
[Regulatory possibilities during COVID-19](#)



DATABASES, REGISTERS

[Drug database](#)
[Paramedicines](#)
[Lists](#)
[Withdrawal/suspension](#)

Important note

This presentation (the “Presentation”) has been prepared by PricewaterhouseCoopers Business Solutions (“PwC”) for the Hellenic Association of Pharmaceutical Companies (SfEE), is considered draft and serves only as a basis for discussion.

To the fullest extent permitted by law, PricewaterhouseCoopers Business Solutions S.A. (“PwC”) accepts no duty of care to any third party in connection with the provision of this Presentation and/or any related information or explanation (together, the “Information”). Accordingly, regardless of the form of action, whether in contract, tort (including, without limitation, negligence) or otherwise, and to the extent permitted by applicable law, PwC accepts no liability of any kind to any third party and disclaims all responsibility for the consequences of any third party acting or refraining to act in reliance on the Information.

The information used by PwC in preparing this Presentation has been obtained from a variety of sources as indicated within the Presentation. While our work may have involved analysis of financial information and/or accounting records, it has not included an audit in accordance with generally accepted auditing standards. Moreover, except where otherwise stated in the Presentation, we have not subjected in the Presentation to checking or verification procedures.

Our conclusions are based upon the information available as at the date of the Presentation. Economic conditions, market factors and changes in the performance of the business may result in our conclusions becoming quickly outdated and may require updating from time to time or before any major decisions are taken based on the Presentation.

Our work is not complete and as a result this draft Presentation may not represent our final findings or conclusions. Amongst other things, receiving final comments from management remains outstanding.

As a result, this draft Presentation should not be relied upon by anyone for any purpose whatsoever.

Thank you

pwc.com

© 2020 PricewaterhouseCoopers Business Solutions SA. All rights reserved. PwC refers to the Greece member firm, and may sometimes refer to the PwC network. Each member firm is a separate legal entity. Please see www.pwc.com/structure for further details.