SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

Q 11: Additional comments on key levers for PHASE II-IV studies (optional) (PHARMA, BIOTECH, CROs, CTUs, answer for PHASE II-III (2-3) STUDIES) (MEDICAL DEVICE AND ALL OTHERS, answer for PHASE III-IV (3-4) STUDIES) (N=56)

Showing 56 responses

The key criteria are trial record and speed communication in setting up a study
2/12/2012 3:39 PM View respondent's answers Categorize as... œ

Internal Competing studies with ISS as an institution R&D Hospital Administration support Knowldege of populaiton numbers
2/12/2012 2:34 PM View respondent's answers Categorize as... œ

none
1/18/2012 9:59 AM View respondent's answers Categorize as... œ

Quality and delivery are key.
1/17/2012 2:39 PM View respondent's answers Categorize as... œ

As above
1/16/2012 5:04 PM View respondent's answers Categorize as... œ

lkgl
1/13/2012 3:10 PM View respondent's answers Categorize as... œ

none
1/4/2012 1:07 PM View respondent's answers Categorize as... œ

Approval times, IEC, Reg Authorities as well as financial contract signature are essential time periods for a quick start up. We need to improve this in Europe if we want to be competitive with other areas in the world. Despite the European Directive, the framework is not common, neither the timelines nor the documents required. Translations into local language are also a stopper when we
SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

are compared to englihs native speaking contries. IECs, RRAA should accept
doucment in english which will save a lot of time and costs.
1/2/2012 12:39 AM View respondent's answers Categorize as... œ

Potential market size and patient availability
12/27/2011 10:35 PM View respondent's answers Categorize as... œ

Direct cost is not the main driver as speed of enrollment has more impact on
overall cost and it makes speed, both in start up phase and enrollment phase, the
main driver.
12/23/2011 2:11 PM View respondent's answers Categorize as... œ

Cost is not the main driver within European countries. It matters a lot in study
allocation in Europe vs. other regions.
12/21/2011 5:50 PM View respondent's answers Categorize as... œ

Regulatory constraints are a key lever to take the decision.
12/21/2011 1:53 PM View respondent's answers Categorize as... œ

O
12/19/2011 11:42 AM View respondent's answers Categorize as... œ

Of course we cannot place any study at a site that does not have the necessary
equipment.
12/19/2011 10:13 AM View respondent's answers Categorize as... œ

for phase II studies, which are based on non clinical endpoint the availability and
the experience with the requested technologic equipment is crucial for the
selection process
11/17/2011 2:53 AM View respondent's answers Categorize as... œ

Accrual capacities
11/15/2011 4:04 PM View respondent's answers Categorize as... œ

none
11/11/2011 4:00 PM View respondent's answers Categorize as... œ

Pharma industry in later phase are more interested KOL (key opinion leaders),
because of what the selection of the site is more dependent from investigator
selection. If CRO is responsible for selection of the site the mail criteria for
selection is usually, the cost and available pool of patient.
11/7/2011 6:23 PM View respondent's answers Categorize as... œ

No additional comments
SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

11/7/2011 10:23 AM View respondent's answers Categorize as... regulatory environment
11/1/2011 6:37 PM View respondent's answers Categorize as... Medical device studies tend to be faster to activate given our current legislative environment in Ireland.
11/1/2011 2:04 PM View respondent's answers Categorize as... Historical enrollment and cycle time very important
10/31/2011 1:22 PM View respondent's answers Categorize as... For Phase II and beyond enrollment potential (with per patient costs already determined) drives almost every decision.
10/29/2011 7:28 PM View respondent's answers Categorize as... slow enrollers might not be invited to new studies; also sites in which IRB/CA is too long will not be priority. The company invest on Study coordination training on new sites.
10/26/2011 4:40 PM View respondent's answers Categorize as... Patient access
10/26/2011 1:50 PM View respondent's answers Categorize as... As for all studies (mainly Phase II and III) the biggest hurdle is the admin. time approval
10/26/2011 11:37 AM View respondent's answers Categorize as... Require a strong interdepartmental relationship and experience in use of our product as it is technically demanding.
10/25/2011 8:19 AM View respondent's answers Categorize as... Investigator dependent
10/24/2011 8:14 PM View respondent's answers Categorize as... I always take into account the infrastructure (Hospital Unit dependent) related to the protocol to accept the trial
10/24/2011 1:37 PM View respondent's answers Categorize as... NA
10/24/2011 12:40 PM View respondent's answers Categorize as...
SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

10/24/2011 11:19 AM View respondent's answers Categorize as... œ
None
10/24/2011 8:03 AM View respondent's answers Categorize as... œ
Working on. Phase1/2 studies, preference is for rapid EC/ HA process
10/24/2011 2:04 AM View respondent's answers Categorize as... œ
our great interest is investigation
10/22/2011 7:30 PM View respondent's answers Categorize as... œ
Patient population, investigator support to research, R&D set up time for contracts in the UK
10/22/2011 11:52 AM View respondent's answers Categorize as... œ
none
10/21/2011 3:39 PM View respondent's answers Categorize as... œ
competitive environment
10/21/2011 12:40 PM View respondent's answers Categorize as... œ
Planning in which countries going to market requires a specific number of study patients in this county (e.g. Taiwan)
10/21/2011 10:14 AM View respondent's answers Categorize as... œ
Additional criteria for trial site selection are: experience in inspections, GCP-compliance, adequate archiving facilities regarding source data and study documents
10/21/2011 10:05 AM View respondent's answers Categorize as... œ
NA
10/21/2011 8:16 AM View respondent's answers Categorize as... œ
none
10/21/2011 5:07 AM View respondent's answers Categorize as... œ
none
10/20/2011 11:30 PM View respondent's answers Categorize as... œ
internal competition- strategical geographical deployment
10/20/2011 6:46 PM View respondent's answers Categorize as... œ
Number of competing studies in the region are also a key decision factor
10/20/2011 5:52 PM View respondent's answers Categorize as... œ
SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

Performance in previous trials
10/20/2011 2:43 PM View respondent's answers Categorize as... ø
No
10/17/2011 3:03 PM View respondent's answers Categorize as... ø
No
10/14/2011 12:28 PM View respondent's answers Categorize as... ø

More studies are run in top six markets following the financial crisis.
10/13/2011 9:03 PM View respondent's answers Categorize as... ø

NA
10/13/2011 4:50 PM View respondent's answers Categorize as... ø

We are NGO and patient's leadr.
10/6/2011 10:40 AM View respondent's answers Categorize as... ø

Competitive trials are key factor in country selection
10/5/2011 5:44 PM View respondent's answers Categorize as... ø

Company sales figures from the relevant market.
10/5/2011 12:14 PM View respondent's answers Categorize as... ø

Contract negotiation with hospital administration/lawyers take too long + ethics committee issues --> these are the two reasons why Italy is often NOT selected. Hospital administration is slow and unreasonable.
5/21/2011 9:48 AM View respondent's answers Categorize as... ø

The environment and costs probably contribute more to the country choice. In a given country the unit and investigator items are of the most relevance when choosing sites, as the budgets are generally consistent across sites.
5/11/2011 6:00 PM View respondent's answers Categorize as... ø

No comments
5/9/2011 2:48 PM View respondent's answers Categorize as... ø
Q25: Please provide your final comments on improvements you would like to see (N=253)

- Increase speed for the signature of site agreements - To remove the need for approvals other than that of the reference EC's and the HA's. For example in Span, some regions require the extra approval of a Regional EC. - To facilitate the conduct of phase IV trials, especially prospective observational studies with a unique and friendly regulation per country

2/13/2012 4:13 PM View respondent's answers Categorize as... œ

More centres of expertise could become part of disease networks
2/12/2012 3:44 PM View respondent's answers Categorize as... œ

We still have to work too much with national regulators, and it would be much preferred to have a genuine centralized regulation for the EEA In the UK the centralized R&D system for permissions is good in concept but poor in execution
2/12/2012 3:32 PM View respondent's answers Categorize as... œ

Ethics Approval process in Italy is an error! Last Patient was already in, we could not get approval. Deregistration was performed before the EC approves the Study! For multiple-trial site, single opinion should be applied like France, Germany, UK
2/11/2012 6:19 PM View respondent's answers Categorize as... œ

transparency and accuracy of information needed
2/1/2012 5:25 PM View respondent's answers Categorize as... œ

No comments
1/24/2012 10:38 AM View respondent's answers Categorize as... œ

Please try to standardize contract per country for all pharma companies as well as Patient Information/informed consent template in Europe - it would given us more strength in Europe versus emerging markets. Thanks for taking this into consideration.
1/22/2012 3:27 PM View respondent's answers Categorize as... œ

Quicker EC/RA handling times; more flexible handling and approval processes.
1/20/2012 3:44 PM View respondent's answers Categorize as... œ

tbd
1/18/2012 10:06 AM View respondent's answers Categorize as... œ

shorter EC/CA approval timelines, better insight in patient potential per country/site, clear insight in best performing sites
1/18/2012 9:58 AM View respondent's answers Categorize as... œ

This is Italy specific where I have no direct experience therefore I cannot answer this question
1/17/2012 7:28 PM View respondent's answers Categorize as... œ

Burocracy should be ireduce in EU. One unique contract with the sites. One Central Europe Ethics Committee. Provide time to Investigators and resources will also help to develop EU in Clinical Trials versus other geographical areas.
1/17/2012 2:56 PM View respondent's answers Categorize as... œ

Central CT approval procedure would be a big improvement.
1/17/2012 2:50 PM View respondent's answers Categorize as... œ

- 
1/17/2012 9:25 AM View respondent's answers Categorize as... œ

tax benefits for clinical research
1/16/2012 2:48 PM View respondent's answers Categorize as... œ

As above
1/16/2012 10:55 AM View respondent's answers Categorize as... œ

more standatdisation and transparency
1/13/2012 1:17 PM View respondent's answers Categorize as... œ

na
1/13/2012 10:38 AM View respondent's answers Categorize as... œ

Harmonization between European countries
1/4/2012 6:00 PM View respondent's answers Categorize as... œ

Unable to answer question 1 on this page, so have split equally to allow me to complete the survey.
1/4/2012 1:16 PM View respondent's answers Categorize as... œ

Central EU wide EC approvals that will limit the additional country approvals required
1/3/2012 6:08 PM View respondent's answers Categorize as... œ

Predictability and transparency
SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

1/3/2012 5:37 PM View respondent's answers Categorize as... œ

No additional comments.
1/3/2012 4:33 PM View respondent's answers Categorize as... œ

Experience of investigators/staff is considered one of the most valuable features. Other important aspect is that recruitment committment has been achieved in previous trials, with high quality
1/3/2012 3:49 PM View respondent's answers Categorize as... œ

O more open survey to key five countries in Europe will be worth.
1/3/2012 11:59 AM View respondent's answers Categorize as... œ

question not clear
1/3/2012 11:46 AM View respondent's answers Categorize as... œ

Improvements: Hospitals having dedicated CR units; Administrations understanding the need for physicians and nurses to have time dedicated exclusively to research; Administration not taking all the money from CT
1/3/2012 11:35 AM View respondent's answers Categorize as... œ

No comments
1/3/2012 11:25 AM View respondent's answers Categorize as... œ

None
1/3/2012 11:19 AM View respondent's answers Categorize as... œ

Patient's fees are one of the big aspect to take into account
1/3/2012 10:02 AM View respondent's answers Categorize as... œ

n/a
1/2/2012 12:31 PM View respondent's answers Categorize as... œ

No comments
1/2/2012 11:07 AM View respondent's answers Categorize as... œ

Convetions in hospitals has to be more quicker.
1/2/2012 8:57 AM View respondent's answers Categorize as... œ

IEC and documents required should be homogenised across Europe, impacting costs and timelines
1/2/2012 12:50 AM View respondent's answers Categorize as... œ

Information for Italy is not accurate as my experience is not much working in this country
Currently I see no improvements
12/27/2011 10:43 PM View respondent's answers Categorize as... ø

nothing else
12/23/2011 3:28 PM View respondent's answers Categorize as... ø

In general, EU is in a good shape for running clinical trials. The main aspect is to be able to get that instutions would support clinical research and recognize the role of an research proffesional versus a health care professional using the free time to work as an investigator
12/22/2011 12:16 PM View respondent's answers Categorize as... ø

More standardisation across Europe with regards to SUSAR reporting in Trials to investigaor and ECs
12/22/2011 9:54 AM View respondent's answers Categorize as... ø

Having infromation for each site/department/investigator regarding equipment, recruitment rates, investigator experince and training, timelines for approval and contract would help to better select the ritght sites
12/22/2011 8:48 AM View respondent's answers Categorize as... ø

Input related to Italy are guesses: NO personal experience.
12/21/2011 5:59 PM View respondent's answers Categorize as... ø

What about the situation in other european countries? Why you have focused only in Italy? I would have questions more closely related with spanish situation
12/21/2011 4:56 PM View respondent's answers Categorize as... ø

The recruitment rate per center sould be also availabel
12/21/2011 4:55 PM View respondent's answers Categorize as... ø

no additional comments
12/21/2011 4:49 PM View respondent's answers Categorize as... ø

Now
12/21/2011 4:11 PM View respondent's answers Categorize as... ø

The fact not to include Scandinavian countries - at leat under one denominator like 'Nordic countries' is considered as major weakness of this survey!
12/21/2011 3:05 PM View respondent's answers Categorize as... ø

Questions pertaining to cardiology studies in Italy are not relevant to my role
12/21/2011 2:27 PM View respondent's answers Categorize as... ø
Why asking about Italy? What about the other countries? This survey does not seem to me too fair.
12/21/2011 2:03 PM View respondent's answers Categorize as... ø

the whole EU should improve admin. workload in approval processes and gain efficiencies across the region. all countries would benefit
12/21/2011 1:15 PM View respondent's answers Categorize as... ø

Harmonisation in terms of expectations by ECs
12/21/2011 11:24 AM View respondent's answers Categorize as... ø

Bit hard to answer if no experience of all countries.
12/21/2011 7:17 AM View respondent's answers Categorize as... ø

Visibility and transparency of the potential for recruitment at any site.
12/20/2011 8:04 PM View respondent's answers Categorize as... ø

no other recommendations
12/20/2011 7:26 PM View respondent's answers Categorize as... ø

NA
12/20/2011 1:23 PM View respondent's answers Categorize as... ø

None
12/20/2011 12:26 PM View respondent's answers Categorize as... ø

Single CTA, single country approval to cover all EU countries. Same for Ethics Committee.
12/19/2011 10:27 PM View respondent's answers Categorize as... ø

Harmonized submission and approval time between countries
12/19/2011 9:48 PM View respondent's answers Categorize as... ø

faster start up times
12/19/2011 4:54 PM View respondent's answers Categorize as... ø

no recommendations
12/19/2011 4:46 PM View respondent's answers Categorize as... ø

None
12/19/2011 1:44 PM View respondent's answers Categorize as... ø

None
12/19/2011 12:22 PM View respondent's answers Categorize as... ø
I did not find all of the questions clear. Also, the different weight of the different criteria leading to country and site selection vary from site to site. This is a much more complex discussion than one can capture in a few numbers. However, as speed of execution is becoming more and more increasingly important, shortening approval timelines is becoming more and more essential.

12/19/2011 11:51 AM View respondent's answers Categorize as... 
none
12/19/2011 11:49 AM View respondent's answers Categorize as... 

Would like to see a more efficient EC approval across EU Would like to see a more homogeneous scientific approach trial across EU
12/18/2011 5:42 PM View respondent's answers Categorize as... 

Thanks so much for your survey so impacting on the "real life" of clinical trials
11/23/2011 11:58 AM View respondent's answers Categorize as... 

central ethic committee approval is needed
11/20/2011 10:07 AM View respondent's answers Categorize as... 

. 11/15/2011 4:14 PM View respondent's answers Categorize as... 

No comments
11/15/2011 12:15 PM View respondent's answers Categorize as... 

no comment
11/14/2011 2:07 PM View respondent's answers Categorize as... 

. 11/14/2011 11:08 AM View respondent's answers Categorize as... 

Insurance coverage
11/14/2011 8:08 AM View respondent's answers Categorize as... 

to speed authorization time (EC and CTRA)
11/13/2011 10:07 PM View respondent's answers Categorize as... 

none
11/11/2011 4:11 PM View respondent's answers Categorize as... 

none
11/9/2011 3:40 PM View respondent's answers Categorize as...
SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

done
11/8/2011 6:20 PM View respondent’s answers Categorize as... ó

better transparency of information regarding EC regulations, easier contracting with hospital, smooth authorization of clinical trial, better investigator and clinical trial staff responsiveness.
11/7/2011 6:40 PM View respondent’s answers Categorize as... ó

European Guidelines and Harmonisation of Clinical Trials
11/7/2011 10:32 AM View respondent's answers Categorize as... ó

Ethical and regulatory timelines are definitively the most limiting factor and urgent improvements are needed. However logistical and organizational aspects need to be addressed as well, in order to make trials more feasible at local level.
11/6/2011 5:39 PM View respondent's answers Categorize as... ó

None
11/6/2011 2:18 PM View respondent’s answers Categorize as... ó

Relevant information about facilities, equipment... available on the hospital's web site is good idea. Also, it could be useful that hospital's administrations promote and enhance the service and physicians involved in clinical trials
11/4/2011 4:50 PM View respondent's answers Categorize as... ó

Single Ethics Committee. Defined (respected) timing for contractual finalization
11/4/2011 10:26 AM View respondent's answers Categorize as... ó

Experience and training in clinical trials
11/2/2011 5:37 PM View respondent's answers Categorize as... ó

Main point: contracting process should be smoother
11/2/2011 3:45 PM View respondent's answers Categorize as... ó

Regulatory and administrative approval processes at hospital level are the critical steps for starting-up clinical trials in Italy.
11/2/2011 11:35 AM View respondent's answers Categorize as... ó

In my opinion the best is to have ONE EC approval for all sites participating in the multicenter clinical trials.
11/2/2011 7:52 AM View respondent's answers Categorize as... ó

speed and transparency in the IRB - regulatory approval process
11/1/2011 8:12 PM View respondent's answers Categorize as... ó
Regulatory environment reliability, speediness Availability of dedicated resources at the sites Foreseeable enrollments
11/1/2011 6:50 PM View respondent's answers Categorize as... ø

Country ethics and regulatory transparency.
11/1/2011 2:12 PM View respondent's answers Categorize as... ø

Less bureaucracy and fewer delays
11/1/2011 7:20 AM View respondent's answers Categorize as... ø

frequent investigators’ meeting
11/1/2011 3:45 AM View respondent's answers Categorize as... ø

no further comment
10/31/2011 3:42 PM View respondent's answers Categorize as... ø

Why the specific focus on Italy? Scandinavia, Finland and Baltic States completely missing in the survey
10/31/2011 1:29 PM View respondent's answers Categorize as... ø

... 10/31/2011 11:55 AM View respondent's answers Categorize as... ø

The general problem for Italy is that setting up the sites is slow
10/31/2011 8:41 AM View respondent's answers Categorize as... ø

Definitely having one single centralized Ethics Review Committee for the entire Country, and having a more efficient local bureaucracy will help a lot for Italian sites to be more competitive.
10/30/2011 4:07 PM View respondent's answers Categorize as... ø

I think this initiative is a great start. Improving uniformity in the contractual and ethics committees between sites would be a very important step to improving the ease of running trials in Italy.
10/29/2011 7:39 PM View respondent's answers Categorize as... ø

Good initiative.
10/29/2011 10:13 AM View respondent's answers Categorize as... ø

no additional comments
10/29/2011 9:50 AM View respondent's answers Categorize as... ø

More active investigator involvement.
10/29/2011 3:30 AM View respondent's answers Categorize as... ø
SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

It would be necessary more rapid Ethic Commitee trails approval
10/28/2011 8:26 AM View respondent's answers Categorize as... oe

Although Italy is an extremely high performing county in relation to recruitment/retention, the timelines for EC approval and copious site training holds them back from being the leader in Europe in my opinion.
10/27/2011 8:47 PM View respondent's answers Categorize as... oe

Improve training and understanding of clinical trials at sites. Improve knowledge of importance of timeliness of data report. Hospital policy makers should implement a policy to facilitate hiring of clinical research professionals in their clinical trial/research units.
10/27/2011 5:27 PM View respondent's answers Categorize as... oe

Two main aspect to improve: quality of the selected centres and of monitoring and burocracy
10/27/2011 1:07 PM View respondent's answers Categorize as... oe

In multinational / multicentric trials is very important the role of the principal investigator, not commented in this survey. The approval/administrative process at any level should improve in all Europe. What about east /west trials in Europe, are we really including patients at the same conditions?.
10/27/2011 10:21 AM View respondent's answers Categorize as... oe

Speed up approval process, decrease bureacracy train physcians in trial conduction
10/26/2011 8:47 PM View respondent's answers Categorize as... oe

Improvement in contracting process for clinical trials would be of great help
10/26/2011 6:51 PM View respondent's answers Categorize as... oe

some questions are difficult to be answered
10/26/2011 5:14 PM View respondent's answers Categorize as... oe

very good discussion
10/26/2011 4:50 PM View respondent's answers Categorize as... oe

Mainly admin. Approval times
10/26/2011 4:37 PM View respondent's answers Categorize as... oe

No specific recommendations
10/26/2011 2:27 PM View respondent's answers Categorize as... oe
Nothing to add
10/26/2011 1:54 PM View respondent's answers Categorize as... ø

Every clinical site which participates in clinical trials should install at least one experienced person or a department acting as an interface to sponsors and authorities which is responsible for professional handling of all basic study related formal issues
10/26/2011 1:22 PM View respondent's answers Categorize as... ø

Good survey
10/26/2011 12:08 PM View respondent's answers Categorize as... ø

nothing else
10/26/2011 12:05 PM View respondent's answers Categorize as... ø

less bureaucracy, easy ethical committee, an italicina network for specific trials
10/26/2011 9:35 AM View respondent's answers Categorize as... ø

Changes described are very much welcomed
10/26/2011 9:15 AM View respondent's answers Categorize as... ø

none
10/26/2011 7:14 AM View respondent's answers Categorize as... ø

People sitting in the IRB committee should be more knowledgeable about studies
10/25/2011 9:30 PM View respondent's answers Categorize as... ø

ECs procedures similar hospital by hospital (national harmonization) good knowledge of GCP needed for MD and nurses involved in the clinical trials publication planning implemented for each clinical trial
10/25/2011 9:28 PM View respondent's answers Categorize as... ø

Thank you
10/25/2011 8:46 PM View respondent's answers Categorize as... ø

Nothing to add
10/25/2011 6:58 PM View respondent's answers Categorize as... ø

To promote a more structured organisation and centralised information
10/25/2011 6:35 PM View respondent's answers Categorize as... ø

Italy is doing quite well. Less bureaucracy, faster regulatory issues processing and unique IRB approval for all centers would definitely improve the current situation
The arduous process of ethics committee and contracting along with variable investigators' engagement make Italy a rather unreliable country for research.

More involvement of academic Trial PI on site recruitment

more coordination / approval guarantee by EU authority for multi-center / multi-country trials

EC and Insurance

no suggestions

Many years ago we worked in Italy and we don’t have good experience with the sites (much promises and bad results)

Study nurses in hospital staff would be one of the main "desiderata" to conduct clinical trials

I do not have any at this time.

Across the board harmonization in the implementation of the EU directive. Transparency in the outcomes of completed trials/ investigator inspections/sponsor/CRO inspections

The European Directive has made things much more complicated than they used to be, particularly regarding independent trials...

Relevant Investigator and Center specific information easily available for all European centers would be of most importance for clinical trial decision planners and would decrease the inefficiency of clinical development time.
SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

10/24/2011 2:02 PM View respondent's answers Categorize as... ø
define single contract, more study coordinator support, strongly push companies in informatics.

10/24/2011 1:35 PM View respondent's answers Categorize as... ø

no comments
10/24/2011 1:22 PM View respondent's answers Categorize as... ø

Nothing more to add
10/24/2011 1:15 PM View respondent's answers Categorize as... ø

more transparency and reliable information on recruitment potential would be a great help.
10/24/2011 1:05 PM View respondent's answers Categorize as... ø

Less bureaucracy
10/24/2011 12:51 PM View respondent's answers Categorize as... ø

NO COMMENTS
10/24/2011 10:29 AM View respondent's answers Categorize as... ø

More transparency and report on all conducted trials
10/24/2011 9:43 AM View respondent's answers Categorize as... ø

None
10/24/2011 8:14 AM View respondent's answers Categorize as... ø

I have no idea on Italian cardiology as I belong to other specialty
10/23/2011 10:03 PM View respondent's answers Categorize as... ø

n/a
10/23/2011 7:17 PM View respondent's answers Categorize as... ø

no
10/22/2011 10:01 PM View respondent's answers Categorize as... ø

my site now is improving the interest in the clinical trial, with the support of the university, and they did a foundation for clinical trial and research which has interest in all the medical specialties
10/22/2011 7:46 PM View respondent's answers Categorize as... ø

done
10/22/2011 5:41 PM View respondent's answers Categorize as... ø
REC approval and information will assist in site selection and this information is not easily available to academic institutions.

10/22/2011 12:07 PM View respondent's answers Categorize as... œ

thanks
10/21/2011 5:41 PM View respondent's answers Categorize as... œ

Improve transparency and flexibility in handling trials, less, more effort in getting the best for patients.

10/21/2011 5:13 PM View respondent's answers Categorize as... œ

Transparency and predictability is core for regulatory and start-up process. Investigators’ attitude can make up for the deficiencies in the regulatory process.

10/21/2011 4:26 PM View respondent's answers Categorize as... œ

Less bureaucracy at the sites
10/21/2011 4:26 PM View respondent's answers Categorize as... œ

Access to general data about the patient population would be very helpful. Harmonisation of the MoH/CEC processes among EU.

10/21/2011 2:54 PM View respondent's answers Categorize as... œ

The CTA and local CA in Italy is truly an obstacle to effectively expanding clinical trial activities in Italy.

10/21/2011 2:37 PM View respondent's answers Categorize as... œ

Good luck
10/21/2011 2:33 PM View respondent's answers Categorize as... œ

better HA and EC submission and approval process in EU, too many differences and country specific details

10/21/2011 1:06 PM View respondent's answers Categorize as... œ

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hanks
10/21/2011 5:41 PM View respondent's answers Categorize as...

Improve transparency and flexibility in handling trials, less , more effort in gettin The best for patients
10/21/2011 5:13 PM View respondent's answers Categorize as...

Transparency and predictability is core for regulaotry and start- up process. Investors attitude can make up for the deficiencies in the regulatory process
10/21/2011 4:26 PM View respondent's answers Categorize as...

Less burocracy a the sites
10/21/2011 4:26 PM View respondent's answers Categorize as...

Access to general data about the patient population would be very helpful. Harmonisation of the MoH/CEC processes among EU.
10/21/2011 2:54 PM View respondent's answers Categorize as...

The CTA and local CA in Italy is truly an obstacle to effectively expanding clinical trial activities in Italy
10/21/2011 2:37 PM View respondent's answers Categorize as...

Good luck
10/21/2011 2:33 PM View respondent's answers Categorize as...

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I would like to see an improvement in ICH/GCP understanding and Quality at Italian sites. I would suggest mandatory ICH/GCP training for all site personnel at every site. Please send the results of this survey directly to me.
5/9/2011 2:57 PM View respondent's answers Categorize as... α

no comments
5/9/2011 2:38 PM View respondent's answers Categorize as... α
(NB: Auxiliary question whose results were not discussed in paper, but for completeness, comments on question 7 on preferred site lists are provided here)

Q7: Does your organization or institution have a "short list" defining PREFERRED SITES in which trials should be run?
N=53

For phase I we have preferred providers Phase II-IV tend not to be an exclusive list, but we do get pointers as to good centres
2/12/2012 2:26 PM

Short list is available but also new sites will be approached based on internal consultation with local feasibility team and review of internal/external databases.
1/18/2012 9:35 AM

if we already know pathology and sites we use the list of sites according to our experience
1/17/2012 9:47 AM

At country level, we do not have an official short list of preferred sites. However, particularly in some Therapeutic Areas (e.g. Oncology and Urology) we do have sites which we partner preferably.
1/16/2012 4:48 PM

We rely on our country specific teams to select sites after feasibility contact
1/16/2012 10:22 AM

sometimes
1/5/2012 9:55 AM

Database listing all sites participating in any of our trials
1/3/2012 11:23 AM View respondent's answers Categorize as... ø

Yes for Flu trials
1/3/2012 9:48 AM

Yes, in some Therapeutic areas in which we have strong experience where we know which sites are good sites for clinical trials, but there is not a Preferred site list for new indications or therapeutic areas
SURVEY RESPONDER COMMENTS & MEMBERS OF EXPERT PANEL DISCUSSION

1/2/2012 12:26 AM View respondent's answers Categorize as... 
Not in general for all trials
12/30/2011 10:31 AM View respondent's answers Categorize as...
Yes. The list is not official but based in previous experience and performance at the sites
12/22/2011 11:32 AM View respondent's answers Categorize as...
Each therapeutic area has elaborated his own list based on previous experience and a local investigator data base will be ready in the near future
12/21/2011 4:02 PM View respondent's answers Categorize as...
There are some preferred sites, but not a full short-list of trial sites
12/21/2011 3:18 PM View respondent's answers Categorize as...
Yes for Phase I/IIa
12/21/2011 2:15 PM View respondent's answers Categorize as...
we have several sites that we like to work with because they are very professional but for every trial there is not specific target or list of sites preferred. we validate all candidates for every study
12/21/2011 12:53 PM View respondent's answers Categorize as...
We use databases to select best sites.
12/20/2011 5:02 PM View respondent's answers Categorize as...
Situational
12/20/2011 2:14 PM View respondent's answers Categorize as...
No. Desired site profiles are determined to select sites
12/20/2011 1:15 PM View respondent's answers Categorize as...
Not completely. For particular diseases, there will be preferred sites/"black-listed" sites but it does not preclude new sites being approached
12/20/2011 10:38 AM View respondent's answers Categorize as...
We don't have a list but we do spread the word within the company and try to utilise the well-performing sites where possible
12/20/2011 8:42 AM View respondent's answers Categorize as...
There is no list of sites we work with. We do have for each study a list of criteria of what the ideal site looks like for this particular study.
12/19/2011 11:27 AM View respondent's answers Categorize as...
Site selection is based on feasibility. We do, of course, select sites that have performed well for us previously but we are also always looking for new sites. We do not go back to non performing sites
12/19/2011 10:03 AM View respondent's answers Categorize as... ø

No but we have criteria for selecting sites e.g. university hospital with adequate facilities/ equipments and support to investigators (research nurse, etc.)
11/15/2011 3:59 PM View respondent's answers Categorize as... ø

sites are identified and evaluated on potential to participate in studies and are further evaluated for protocol specific participation
11/8/2011 6:04 PM View respondent's answers Categorize as... ø

Not applicable
11/7/2011 10:14 AM View respondent's answers Categorize as... ø

No, it is often dependent on the CRO country and site distribution goals & objectives and balancing with the sponsor's marketing & regulatory needs for the study in questions
11/6/2011 2:07 PM View respondent's answers Categorize as... ø

Please refer to above, depending on the therapeutic field and the development stage of the drug
11/4/2011 9:56 AM View respondent's answers Categorize as... ø

I don't know
10/27/2011 12:51 PM View respondent's answers Categorize as... ø

"Short list" based on previous positive experience (as well as fulfilling other general study criteria) doesexist, however detailed feasibility is conducted and pool of sites expanded, if needed
10/26/2011 6:21 PM View respondent's answers Categorize as... ø

It depends on therapeutical area involved (in same case yes)
10/25/2011 9:02 PM View respondent's answers Categorize as... ø

I don't know
10/25/2011 12:27 PM View respondent's answers Categorize as... ø

same above
10/25/2011 8:21 AM View respondent's answers Categorize as... ø

Yes at the planning stage , short listed countries may change once a regulatory submission has initiated
10/24/2011 7:45 PM View respondent's answers Categorize as... ø
Since I run a Clinical Trial Unit I don’t have this responsibility
10/24/2011 1:26 PM View respondent's answers Categorize as... œ

Yes, but it is informal, according to the Medical Director net of contacts
10/24/2011 9:22 AM View respondent's answers Categorize as... œ

Partially yes, the list is the first source of information but we are not limiting us to the short list
10/21/2011 4:11 PM View respondent's answers Categorize as... œ

Short list is based on own experience in previous trials in same disease entity
10/21/2011 2:05 PM View respondent's answers Categorize as... œ

Not applicable
10/21/2011 10:45 AM View respondent's answers Categorize as... œ

Any clinical trials we check all available sites, as changes may occur from year to year
10/21/2011 8:57 AM View respondent's answers Categorize as... œ

NA
10/20/2011 6:24 PM View respondent's answers Categorize as... œ

To a certain extend for the therapeutic areas we have large experience in
10/20/2011 2:32 PM View respondent's answers Categorize as... œ

depends on extent of experience in the field, for some yes for some no
10/19/2011 3:25 PM View respondent's answers Categorize as... œ

Like a consultant I'm not involved in that issue
10/17/2011 2:37 PM View respondent's answers Categorize as... œ

Affiliates consulted
10/13/2011 5:26 PM View respondent's answers Categorize as... œ

Not really"a list" but a general knowledge/opinion about this.
10/12/2011 5:48 PM View respondent's answers Categorize as... œ

Some companies have a scoring system post trial for measuring performance. In a few cases these are weighted. Its probably more usual for companies to maintain a blacklist
10/10/2011 3:32 PM View respondent's answers Categorize as... œ

Depending on indications-in many cases yes
10/7/2011 8:33 PM View respondent’s answers Categorize as... û

Yes for some specific therapeutic areas
10/5/2011 1:46 PM View respondent’s answers Categorize as... û

Yes but depending on the project, the list can always be re-evaluated and extended.
10/5/2011 1:12 PM View respondent’s answers Categorize as... û

Knowledge of previous experience of well-performing sites is in-house
10/5/2011 11:36 AM View respondent’s answers Categorize as... û

Kind of short list but not strictly followed
10/5/2011 11:24 AM View respondent’s answers Categorize as... û

Yes and no, depend on the indication and study group
5/13/2011 3:56 PM View respondent’s answers Categorize as... û

Not at the Trials Unit, but the CRO and sponsor have lists of sites they have worked with previously and would start with these when setting up trials.
5/11/2011 5:47 PM View respondent’s answers Categorize as... û
Members of 25 Member expert panel with whom results were discussed in in Brussels on November 2012

Clinical Trials Working Group
EFPIA Brussels – Room Trône (6th floor) November 6th 2013

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