Knowledge, Attitude and Practice on Clinical Development and Medical Affairs among DCVMN members: Results of a survey.”

Simonetta Viviani
Webinar on 6 of October
2021
The clinical development represents an essential component of vaccine development to obtain marketing authorization (MA), and possibly WHO PQ (World Health Organization Pre-Qualification) as well as supporting its wide use.

Demonstrating safety and efficacy (or immunogenicity as surrogate marker of efficacy) in humans is the pillar of vaccine clinical development.

Clinical development is a highly regulated matter on:
- General Scientific and methodological aspects https://ichgcp.net/ (E6(Good Clinical Practices), E8 (General Considerations for Clinical Trials), E9 (Statistical Principles for Clinical Trials), E3 (Clinical Study Reports) etc
- Vaccine Specific guidelines and recommendations (i.e. WHO Expert Committee on Biological Standardization-TRS (Technical Report Series on several aspects of vaccine development); USA FDA, EMA, National Regulatory Authorities
Usually recommendations and guidelines are considered **NOT BINDING**

However, if not followed a **strong justification** should be provided to regulatory authorities

Thus performing a successful clinical development of any candidate vaccine requires a strong **scientific, technical, operational and regulatory expertise**

The **scope of this survey** is to evaluate the knowledge, attitude and practice on Clinical Development and Medical Affairs organization and expertise among vaccine manufacturers in developing countries
Methodology

The survey was performed in an anonymous way through the administration of a questionnaire to all 41 DCVMN members.

The questionnaire contained 74 questions specifically designed:

- 1st section aimed to collect information on the organization and the activities conducted by the clinical functions of the company.
- 2nd section aimed to collect information on the trial design ability and on the management of clinical trial documents.
- 3rd section aimed to collect information on clinical trial management, monitoring activities and other related activities.
- 4th section aimed to collect information on the clinical quality aspects.
Results

- A total of **33 compiled questionnaires** were found in the database at the time of database lock.
- At database cleaning activities, **3 questionnaires** were removed as duplicate (same IP address)
- A total of **30 respondents** (different IP address) were included in the analysis
- **25 respondents** filled a complete questionnaire
- Three members do not have clinical activities.
- A total of **33/41** provided feedback (**3 with no clinical activities**) on the survey
Results of the 1st section aimed to collect information on the organization and overall activities conducted by the clinical functions of the company
My Clinical Department denomination is

- Clinical Affairs: 3.33% (1 response)
- Clinical Development & Medical Affairs: 16.67% (5 responses)
- Clinical Development: 20.00% (6 responses)
- Clinical & Medical Affairs: 23.33% (7 responses)
- Clinical Research & Development: 23.33% (7 responses)
- Other (please specify): 13.33% (4 responses)

TOTAL: 30 responses
DCVMN Companies and total number of employees in clinical department by presence of at least one MD or PhD

<table>
<thead>
<tr>
<th>Total number of employees</th>
<th>Presence of at least one MD</th>
<th>Presence of at least one PhD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10 (13 responders)</td>
<td>7/13</td>
<td>6/13</td>
</tr>
<tr>
<td>&gt;10-20 (8 responders)</td>
<td>7/8</td>
<td>7/8</td>
</tr>
<tr>
<td>&gt;20 (9 responders)</td>
<td>7/9</td>
<td>7/9</td>
</tr>
<tr>
<td>Total responders</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>
Vaccines licensed (with Marketing Authorization) in foreign countries, including WHO Prequalified vaccines (Q17)

Answered: 27    Skipped: 3

<table>
<thead>
<tr>
<th>ANSWER CHOICES</th>
<th>RESPONSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5</td>
<td>77.79%</td>
</tr>
<tr>
<td>6-10</td>
<td>7.41%</td>
</tr>
<tr>
<td>&gt; 10</td>
<td>14.81%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>27</td>
</tr>
</tbody>
</table>

Vaccines licensed (Marketing Authorization) in the national market (Q16)

Answered: 29    Skipped: 1

<table>
<thead>
<tr>
<th>ANSWER CHOICES</th>
<th>RESPONSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5</td>
<td>51.72%</td>
</tr>
<tr>
<td>6-10</td>
<td>20.69%</td>
</tr>
<tr>
<td>&gt; 10</td>
<td>27.59%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>29</td>
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</table>
### Number of candidate vaccines in clinical development by number of employees in clinical department

Answered: 30    Skipped: 0

<table>
<thead>
<tr>
<th></th>
<th>0</th>
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<th>2</th>
<th>3-5</th>
<th>&gt; 5</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2: 1-5</td>
<td>30.00%</td>
<td>20.00%</td>
<td>0.00%</td>
<td>40.00%</td>
<td>10.00%</td>
<td>33.33%</td>
</tr>
<tr>
<td>Q2: 6-10</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>66.67%</td>
<td>33.33%</td>
<td>10.00%</td>
</tr>
<tr>
<td>Q2: 11-20</td>
<td>25.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>12.50%</td>
<td>62.50%</td>
<td>26.67%</td>
</tr>
<tr>
<td>Q2: &gt; 20</td>
<td>11.11%</td>
<td>0.00%</td>
<td>22.22%</td>
<td>22.22%</td>
<td>44.44%</td>
<td>30.00%</td>
</tr>
</tbody>
</table>

| Total Respondents| 6      | 2      | 2      | 0      | 11     | 30        |

#### Number of employees in clinical department

- Q2: 1-5
- Q2: 6-10
- Q2: 11-20
- Q2: > 20

#### Number of vaccines in clinical development

- 0
- 1
- 2
- 3-5
- > 5

**Powered by SurveyMonkey**
Phase I-IV clinical trials initiated in 2019, 2020 and 2021 by number of employees in the clinical department

Answered: 30    Skipped: 0
Clinical trials conducted in foreign countries since 2015 (Q11)

Common Technical Documents or other registration dossier submitted to your National Regulatory Authorities since 2015 (Q13)

Common Technical Document or Product Summary File submitted for WHO PQ since 2015 (Q14)
Number of clinical trials conducted in foreign countries since 2010 by number of employees in the clinical department

Answered: 30    Skipped: 0
CTD submission since 2015 by number of employees in clinical department

Number of registration dossier (CTD) submitted to National Regulatory Authorities since 2015 by number of employees in the clinical department

Number of registration dossier (CTD) submitted to foreign National Regulatory Authorities since 2015 by number of employees in the clinical department
Articles published in peer-reviewed journals as a result of clinical trials performed by your clinical/medical department since 2010 by number of PhDs in clinical dpt

Common Technical Document or Product Summary File or other Registration dossiers (CTD or PSF) submitted by your company for WHO PQ since 2015 by number of PhDs in clinical dpt
Summary Results of the 1° survey section: overall clinical related activities

- All respondents have one or more vaccines licensed in the national market, foreign markets or WHO Prequalified

- All respondents have high output clinical activity not clearly associated with the number of total employees in the clinical Department, except for the number of clinical trials conducted in foreign countries since 2010

- Published articles since 2010 and number of CTDs submitted to WHO since 2015 were associated with number of PhDs employed in the clinical Department
Results of the 2nd section aimed to collect information on the trial design ability and on the management of clinical trial documents
The clinical development plan is a document written for each candidate vaccine (Q18)

Before starting a clinical trial my company requires the approval from local Ethic Committee (Q19)

Answered: 26    Skipped: 4

<table>
<thead>
<tr>
<th>ANSWER CHOICES</th>
<th>RESPONSES</th>
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</thead>
<tbody>
<tr>
<td>Always</td>
<td>69.23%</td>
</tr>
<tr>
<td>Sometimes</td>
<td>23.08%</td>
</tr>
<tr>
<td>Never</td>
<td>7.69%</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
</tr>
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</table>
Clinical trial documents required by local Ethical Committees to initiate a clinical trial (Q20)

Answered: 26  Skipped: 4
How many primary objectives do you set in designing a clinical trial protocol (Q21)

Answered: 25    Skipped: 5

The sample size for a clinical trial should be calculated taking into account (Q22):

Answered: 26    Skipped: 4
Number of primary objectives in Clinical Trial Protocol design by number of PhDs in clinical department

Sample size calculation considerations by number of PhDs in the clinical department

Answered: 25  Skipped: 5

No of primary objectives

- Green: 1
- Blue: 2-3
- Yellow: >3

No of PhDs in clinical dpt

- Q4: 0
- Q4: 1
- Q4: 2-5
- Q4: 6-10
- Q4: >10

- The safety objective
- The primary objective
- The most important secondary objective
- The immunogenicity objective
- The efficacy objective
In a clinical trial for how long after study vaccine administration are solicited selected Adverse Events (Local and Systemic post-immunization reactions) collected? (Q23)

Answered: 25  Skipped: 5
In a clinical trial for how long after study vaccine administration are unsolicited Adverse Events collected (Q25)?

Answered: 26   Skipped: 4

...and Serious Adverse Events (Q26)?
In a clinical trial testing a recombinant or vectored vaccine Serious Adverse Events are collected for: (Q27)

In a clinical trial testing an inactivated vaccine Serious Adverse Events are collected for: (Q28)

Answered: 26    Skipped: 4
Does your company's clinical department always collect AEs and SAEs in clinical trials? (Q29)

Answered: 26    Skipped: 4

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<td>3.85%</td>
</tr>
<tr>
<td>Never</td>
<td>3.85%</td>
</tr>
<tr>
<td>Only AEs</td>
<td>3.85%</td>
</tr>
<tr>
<td>Only SAEs</td>
<td>3.85%</td>
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<tr>
<td>TOTAL</td>
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The Informed Consent Form may require translation in local languages. How does your clinical team make sure that the translation is properly done? (Q31)

Answered: 25  Skipped: 5

When during a clinical trial subjects or subject's parents/legal guardians should sign the ICF? (Q32)

Answered: 26  Skipped: 4
The Statistical Analysis Plan (SAP) is finalized (Q34):

Answered: 25    Skipped: 5

The Statistical Analysis Report (SAR) should be finalized at (Q35):
Number of protocol amendments issued on average for each clinical trial protocol (Q36)

Answered: 26    Skipped: 4
Clinical Study Report content should first of all comply with (Please rank from most to least important from 1 to 5)-Q37

Answered: 26  Skipped: 4

<table>
<thead>
<tr>
<th>Declaration of Helsinki</th>
<th>Company Policy</th>
<th>ICH</th>
<th>Company Management Recommendations</th>
<th>Clinical SOPs</th>
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<td>0.00% 0 3.85% 1 3.85% 1 23.08% 6 69.23% 18</td>
<td>15.38% 4 19.23% 5 30.77% 8 23.08% 6 11.54% 3</td>
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<tr>
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<td>23.08% 6</td>
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<td>50.00% 13</td>
<td>3.85% 1</td>
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<td>3.81</td>
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<td>23.08% 6</td>
<td>11.54% 3</td>
<td>26</td>
<td>3.04</td>
</tr>
</tbody>
</table>
Are clinical trials posted in public clinical trials registry platforms? (Q38)

Answered: 26  Skipped: 4

Platform where clinical trials usually posted (Q39)

Answered: 25  Skipped: 5

<table>
<thead>
<tr>
<th>ANSWER CHOICES</th>
<th>RESPONSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>88.46%</td>
</tr>
<tr>
<td>Sometimes</td>
<td>7.69%</td>
</tr>
<tr>
<td>Never</td>
<td>3.85%</td>
</tr>
<tr>
<td>TOTAL</td>
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</tbody>
</table>
Summary results of the 2nd section: trial design ability and the management of clinical trial documents

- The majority of respondents retain correct practices in the ethical and methodological aspects of clinical trial design, as well as in the management of clinical trial documents.

- The correct approach of some aspects of the clinical trial design depend upon the number of PhDs employed in the clinical department.

- Some residual pockets of improvement are identified in:
  - Definition and collection of AEs and SAEs during clinical trials
  - ICF process
  - Obligation to register a clinical trial in public registry
  - Statistical analysis flow and CSR compliance
Results of the 3d section aimed to collect information on clinical trial management, monitoring activities and other related activities.
Selection of investigators and clinical study sites is outsourced to Clinical Research Organizations (CROs) - Q40

In your company, when is checked that Clinical Site SOPs are in place? (Q42)

Answered: 26  Skipped: 4
Criteria adopted by your company to select clinical study sites (please rank according to relevance) - Q41

Answered: 26    Skipped: 4

Criteria

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>TOTAL</th>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site enrollment rate and population</td>
<td>15.38%</td>
<td>15.38%</td>
<td>23.06%</td>
<td>30.77%</td>
<td>15.38%</td>
<td>0.00%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigator and site team qualifications</td>
<td>61.54%</td>
<td>7.69%</td>
<td>15.38%</td>
<td>11.54%</td>
<td>3.85%</td>
<td>0.00%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td>0.00%</td>
<td>11.54%</td>
<td>19.23%</td>
<td>3.85%</td>
<td>42.31%</td>
<td>23.08%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past performance of investigator and site team</td>
<td>3.85%</td>
<td>46.15%</td>
<td>19.23%</td>
<td>19.23%</td>
<td>3.85%</td>
<td>7.69%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of competing clinical studies</td>
<td>7.69%</td>
<td>3.85%</td>
<td>3.85%</td>
<td>15.38%</td>
<td>23.08%</td>
<td>46.15%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site availability of equipments/structure</td>
<td>11.54%</td>
<td>15.38%</td>
<td>19.23%</td>
<td>19.23%</td>
<td>11.54%</td>
<td>23.08%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Q43: Are clinical study documents written by staff at your company (in house)?

Answered: 26    Skipped: 4
Are clinical trial protocols written by staff at your company (in house)? (Q44)
Answered: 25    Skipped: 5

In your company the responsibility to write the Investigator Brochure (IB) is with... (Q45)
Answered: 26    Skipped: 4

In your company the responsibility to write the Clinical Study Reports is with...(Q46)
Answered: 25    Skipped: 5
Does your company perform clinical trial monitoring activities in house (with its own personnel)? (Q47)

Answered: 25    Skipped: 5

CROs should produce periodical monitoring reports documenting monitoring activities to be reviewed (Q48)

Always performed in house

For some trials

Always outsourced to CRO’s or independent monitors

CRO’s reports are reviewed after each monitoring visit

CROs monitoring reports are reviewed before study end
Are in your company clinical data management and statistical activities outsourced? (Q49)

Answered: 26    Skipped: 4
Which criteria do you think are more relevant to adopt to select CROs? (Please rank from most to least important from 1 to 5) (Q50)

Answered: 26    Skipped: 4

<table>
<thead>
<tr>
<th>Criteria</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>TOTAL</th>
<th>SCORE</th>
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<tbody>
<tr>
<td>CRO's Cost</td>
<td>11.54%</td>
<td>3.85%</td>
<td>15.38%</td>
<td>26.92%</td>
<td>42.31%</td>
<td>26</td>
<td>2.15</td>
</tr>
<tr>
<td>CRO's Quality System</td>
<td>42.31%</td>
<td>26.92%</td>
<td>26.92%</td>
<td>3.85%</td>
<td>0.00%</td>
<td>26</td>
<td>4.08</td>
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<tr>
<td>CRO's working relationship</td>
<td>3.85%</td>
<td>3.85%</td>
<td>7.69%</td>
<td>46.15%</td>
<td>38.46%</td>
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<td>1.88</td>
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<tr>
<td>CRO's Capability</td>
<td>23.08%</td>
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<td>23.08%</td>
<td>11.54%</td>
<td>7.69%</td>
<td>26</td>
<td>3.54</td>
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<tr>
<td>CRO's Experience</td>
<td>19.23%</td>
<td>30.77%</td>
<td>26.92%</td>
<td>11.54%</td>
<td>11.54%</td>
<td>26</td>
<td>3.35</td>
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</tbody>
</table>
Has your clinical department SOPs to select and manage CROs? (Q51)

Answered: 26    Skipped: 4

Does your company perform audits to CROs? (Q52)
In the past 5 years how many CROs were employed by your company for clinical trial monitoring? (Q53)

Answered: 26    Skipped: 4

Can you please rate the level of satisfaction of CROs you employed for overall clinical trials activities in the past 5 years? (Q55)
Please express your level of agreement with the following statement "CROs can perform study management activities according ICH-GCP without the need of Sponsor supervision" (Q54)

Answered: 26    Skipped: 4
Are serological assays to evaluate vaccine immunogenicity performed by your company internal laboratory? (Q56)

Does your company perform qualification visits to select an external lab for immunogenicity evaluation in clinical trials? (Q58)

Answered: 26   Skipped: 4
Which criteria in order of importance does your company adopt to select an external laboratory to perform serological assays for immunogenicity evaluation in clinical trials? (Q57)

Answered: 26  Skipped: 4

<table>
<thead>
<tr>
<th>Criteria</th>
<th>1</th>
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<th>3</th>
<th>4</th>
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<th>7</th>
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<tr>
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<td>11.54%</td>
<td>11.54%</td>
<td>15.38%</td>
<td>15.38%</td>
<td>30.77%</td>
<td>11.54%</td>
<td>3.85%</td>
<td>25</td>
<td>4.08</td>
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<tr>
<td>It is suggested by colleagues</td>
<td>4.17%</td>
<td>8.33%</td>
<td>20.83%</td>
<td>37.50%</td>
<td>16.67%</td>
<td>4.17%</td>
<td>8.33%</td>
<td>24</td>
<td>4.00</td>
</tr>
<tr>
<td>It is known for the published paper</td>
<td>0.00%</td>
<td>23.08%</td>
<td>42.31%</td>
<td>11.54%</td>
<td>11.54%</td>
<td>11.54%</td>
<td>0.00%</td>
<td>26</td>
<td>4.54</td>
</tr>
<tr>
<td>It is a reference WHO lab</td>
<td>53.85%</td>
<td>15.38%</td>
<td>3.85%</td>
<td>7.69%</td>
<td>3.85%</td>
<td>3.85%</td>
<td>11.54%</td>
<td>25</td>
<td>5.50</td>
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<tr>
<td>Our company has an established collaboration with the lab</td>
<td>16.00%</td>
<td>36.00%</td>
<td>12.00%</td>
<td>12.00%</td>
<td>8.00%</td>
<td>12.00%</td>
<td>4.00%</td>
<td>25</td>
<td>4.88</td>
</tr>
<tr>
<td>For personal connection</td>
<td>0.00%</td>
<td>8.00%</td>
<td>4.00%</td>
<td>12.00%</td>
<td>16.00%</td>
<td>20.00%</td>
<td>40.00%</td>
<td>25</td>
<td>2.44</td>
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<tr>
<td>It is a new established lab</td>
<td>16.00%</td>
<td>0.00%</td>
<td>4.00%</td>
<td>4.00%</td>
<td>8.00%</td>
<td>36.00%</td>
<td>32.00%</td>
<td>25</td>
<td>2.76</td>
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Summary Results of the 3d section: clinical trial management, monitoring activities and other related activities

- The majority of respondents outsources one or more trial management activities to CROs as selection of study sites, monitoring and data management and statistics

- Writing of clinical study documents are also outsourced to CROs but to a lesser extent

- The majority of respondents is satisfied with the performances of the CROs employed, although they believe that Sponsor’s supervision is required

- Some pockets of improvement are identified in the process of supervising CROs (i.e. verifying CRO’s SOPs in place, performing audits, etc)
Results of the 4th section aimed to collect information on the clinical quality system in place in the clinical department.
Has your company an approved organizational chart of the Clinical Department? (Q59)

Answered: 25    Skipped: 5

Has your company a Job Description for each employee of the Clinical Department? (Q60)

Answered: 25    Skipped: 5
Has your company update CV's and Training Records for employees in the clinical department? (Q61)

Answered: 25  Skipped: 5

Has your company a Master Clinical Standard Operating Procedure (SOP)? (Q62)
Has your company a set of documented clinical SOPs (Please thick one or more boxes of the corresponding section if SOPs are available) (Q63)

Answered: 25  Skipped: 5
How often your company's Clinical SOPs are reviewed? (Q64)

Answered: 25  Skipped: 5

- Every year
- Every two years
- Every three years
- When changes in one or more SOPs are required

Does your company list of Clinical SOPs include one or more SOPs "On how to manage and report Serious Adverse Events notified during clinical trials"? (Q65)

- Yes
- In preparation
- No
- In process
- Not applicable
Does your company list of Clinical SOPs include one or more SOPs for auditing CROs? (Q66)

In the past 5 years, were Clinical Trial Sites sponsored by your company audited by an Independent Auditor? (Q67)

Answered: 25  Skipped: 5
Has one or more clinical trial sites conducting trials sponsored by your company been inspected by National Regulatory Authority? (Q68)

Answered: 25  Skipped: 5

Has your company one or more SOPs on "how to handle Clinical Trials audits and inspections"? (Q69)
Your company may have appointed a Data Safety Monitoring Board in one of the sponsored clinical trials. Is one or more SOPs in place on "how to appoint and manage a DSMB"? (Q70)

Answered: 25   Skipped: 5

Does your company list of clinical SOPs include one or more SOPs on "how to select and manage an external laboratory to perform human serology for immunogenicity evaluation in clinical trials"? (Q71)
How often in your company is specific training (GCP, PV) delivered to clinical staff? (Q72)

Answered: 25    Skipped: 5

Are staff training records filed in a dedicated folder? (Q73)
In your opinion which kind of training should be considered a priority for clinical personnel involved in conducting clinical trials in your company? (Please rank the most to least important from 1 to 5) (Q74)

Answered: 25    Skipped: 5

<table>
<thead>
<tr>
<th>Training Type</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<tr>
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<td>Laboratory serological assays</td>
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Summary Results of the 4th section: *clinical quality system in place in the clinical department*

- The majority of respondents retains a clinical quality system in place with a set of SOPs concerning the core clinical activities.

- Training to clinical staff is delivered at different intervals or «when deemed necessary».

- As identified by respondents themselves, the areas where training is needed most in order of priority are:
  - ICH-GCP
  - Ethical aspects
  - Design of clinical trials
  - PV
Overall survey conclusions and recommendations

- Majority of respondent has a variety of organizational models and different size of the clinical department

- Some pockets of improvement in the process of designing, planning and conducting clinical trials as well as in the clinical quality aspects were identified

- Delivery of continuos and specific training is highly recommended to tackle the methodological complexity of vaccine clinical development
Thanks for participating!

For any question please contact me at

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