

MINUTES OF THE 9th MEETING OF TECHNICAL COMMITTEE HELD ON 29-10-2013 UNDER THE CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES IN THE LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA ON 03.01.2013

Present:

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| 1. | Dr. Jagdish Prasad,
Director General of Health Services. | Chairman |
| 2. | Dr. Ranjit Roy Chaudhury,
National Professor of Pharmacology,
Former Member, BOG-MCI,
New Delhi. | Member |
| 3. | Dr. Vinod Raina,
Fortis Memorial Research Institute,
SCO-44, Gurgaon. | Member |
| 4. | Dr. Nandini Kumar,
Former Dy. Director (Sr. Grade)
National Institute of Epidemiology, ICMR, Delhi. | Member |
| 5. | Dr. Nikhil Tandon,
Professor, Dept of endocrinology & Metabolism,
AIIMS, New Delhi. | Member |
| 6. | Dr. S.N. Gaur,
Prof. & Head, Dept. of Respiratory Medicine,
V.P. Chest Institute, New Delhi | Member |
| 7. | Dr. B.L. Sherwal,
DDG(M) & Director- Prof,
Dept. of Microbiology,
LHMC & Associated Hospitals, Delhi | |

From CDSCO:

1. Sh. A.K. Pradhan
Deputy Drugs Controller (India)
2. Ms. A Vishala
Deputy Drugs Controller (India)

Dr. Jagdish Prasad, DGHS welcomed the members and briefed them about the outcome of the eighth meeting of the Technical Committee which was held on 30.09.13. The minutes of the eighth meeting approved by the Chairman were already circulated to the members.

The committee was apprised the order of the Hon'ble Supreme Court of India, dated 21.10.2013 in the matter of W.P. (C) No. 33/2012 of Swasthya Adhikar Manch, Indore & Anr Vs. Ministry of Health and Family Welfare &Ors. with WP(C) No. 779/2012 regarding clinical trials. The operative part of the order in respect of 162 global clinical trials which were approved by DCG(I), since November 2011 to 31.8.2013 were placed before the committee. The same is reproduced below:

“Out of 285 applications which have been recommended for approval by NDACs include clinical trials for investigational products relating to Anti-AIDS, Oncology, Cardiology, Neurology, Psychiatry, Metabolism, Endocrinology, etc. NDACs have evaluated carefully pharmacological, toxicological data, clinical data and protocol for the clinical trials including the objective of the study, eligibility criteria of the subjects, treatment, safety and efficacy assessments, etc. Of these 285 applications, DCG(I) has given approval to conduct clinical trials in 162 cases till 31.08.2013.

Out of 162 approvals, 157 approvals were given by the DCG(I) before 31.12.2012 which were prior to directions of this Court on 03.01.2013. The DCG(I) has given the approval to conduct clinical trials in the remaining 5 cases from 01.01.2013 till 31.08.2013 after the approval of the Apex Committee assisted by the Technical Committee.

The above facts show that insofar as 5 cases out of 162 cases which were given approval by DCG(I) are concerned, these 5 cases had undergone the three-tier screening. First by NDACs, then by the Technical Committee and the Apex Committee and thereafter the approval has been given by the DCG(I).

However, as regards 157 approvals which were given by the DCG(I) before 03.01.2013, learned Additional Solicitor General fairly submits that these cases have not been evaluated by the Technical Committee and the Apex Committee. He submits that the Central Government is agreeable that these 157 cases may be evaluated by the Technical Committee and the Apex committee as well, as has been done for the 5 cases for which approval was given after 03.01.2013.

We accept the statement of the learned Additional Solicitor General. We, however, observe that the Technical committee and the Apex Committee while evaluating the above 157 cases shall keep in view all relevant aspects of safety and efficacy particularly in terms of assessment of risk versus benefit to the patients, innovation vis-a-vis existing therapeutic option and unmet medical need in the country.

In the light of the above, it is not possible to pass any order today with regard to 157 cases and the same will be considered after the reports of the Technical Committee and the Apex Committee in respect of 157 cases are submitted before this Court. As regards 5 cases for which approval has been given by the DCG(I) after 03.01.2013, we record and accept the statement of Mr. Siddharth Luthra, learned Additional Solicitor General that before the clinical trials are conducted, appropriate provision shall be made or administrative direction shall be issued which ensures that audio-visual recording of the informed concerned process of the participants is done and the documentation preserved, adhering to the principals of confidentiality. In other words, the clinical trials in respect of five cases shall commence after proper framework is in place concerning audio-visual recording of the informed concerned process and the preservation of documents while adhering to the principals of confidentiality.”

The committee discussed the issue of evaluation of the 157 cases of global clinical trials as per the order of the Hon'ble Supreme court and desired that CDSCO should collect following information in respect of these cases from the applicants:

- Name of the company/sponsor
- Details of the trial
- Details of sites and Investigators
- Present status of trial (Initiated/Ongoing/Completed/Suspended/Not initiated).
- Subject enrolment status.
- Details of SAEs occurred.

The committee desired that the above information should be collected within two weeks and submitted to the Committee, so that deliberation on these cases could be further initiated within 3 weeks. The committee also decided that separate meetings would be organized for evaluation of these 157 cases.

Thereafter the committee evaluated the proposal from CSIR for conducting clinical trial with PA-284 (An IND) in MDR TB, for which, the committee in its 8th meeting held on 30.09.13, noted that subjects in one arm of the study would not receive the standard care and desired that complete protocol of study should be circulated to the members for review. Accordingly, the complete protocol was circulated to the members of the committee via e-mail. The committee deliberated the proposal in detail and opined that study can't be approved in its present form and recommended that the protocol of the study should be modified by deleting first arm of the study in which the trial participants will not receive the standard treatment. This is because, in a scenario if experimental drug is not effective it will not only harm the participants of the arm but also it could lead to develop XDR. Accordingly, the protocol should be modified and submitted to the committee for review.

The committee then evaluated the 34 proposals of clinical trials, out of these 34 proposals there were 14 cases of Global Clinical trials, 2 cases of New drugs and remaining were clinical trial proposals related to fixed dose combinations,

subsequent new drugs, biological, and institutional trial. Detailed information on these proposals as per the prescribed format was forwarded to the members through e-mail. List of these proposals is as under:

Sr. No.	Drug	Names of the Applicant	Division
1	UT-15C	M/s PRA Pvt. Ltd.	GCT
2	UT-15C	M/s PRA Pvt. Ltd.	GCT
3	Daclizumab High Yield Process (DAC HYP), Inj.	M/s Biogen Idec Pvt. Ltd. Gurgaon.	GCT
4	SB4	M/s Quintiles Res. (P) Ltd.	GCT
5	SB2	M/s Quintiles Res. (P) Ltd.	GCT
6	Belimumab (Benlysta™) Inj.	M/s Quintiles Res. (P) Ltd.	GCT
7	Alglucosidase alfa Inj.	M/s Genzyme India (P)	GCT
8	Faster-acting insulin aspart (FIAsp)	M/s Novo Nordisk (P) Ltd.	GCT
9	Faster-acting insulin aspart (FIAsp)	M/s Novo Nordisk (P) Ltd.	GCT
10	Insulin Lispro Mix 25 AND Insulin Lispro Mix 50 Inj.	M/s Eli Lilly Co. (P) Ltd.	GCT
11	Semaglutide	M/s Novo Nordisk (P)	GCT
12	Rituximab Inj.	BIOCAD India (P) Ltd.	GCT
13	Linagliptin	M/s Manipal Accunova (P) Ltd. Manipal, karnataks.	GCT
14	Xprenor (buprenorphine oral lyophilisate)	M/s Clingene International Ltd. Bangalore	GCT
15	VSL#3	Dr. Varsha Gupta, GMCH, Chandigarh	Institutional CT
16	Simvastatin	Dr. Deppak Thappa, GMCH, Chandigarh	Institutional CT
17	Palonosetron	Dr. Yogesh Roy, ESIC-PGIMSR, Delhi	Institutional CT
18	Platelet Rich Plasma	Dr. Aarti Sharma, KGMU, Lucknow	Institutional CT
19	Pulse Steroids	Dr. Nilesh Kolkha, KGMU, Lucknow	Institutional CT
20	Dexlansoprazole	M/s. MSN Labs	NDA
21	Lurasidone	M/s. MSN Labs	NDA

22	FDC of MultiBic potassium-free, MultiBic 2 mmol/l potassium, MultiBic 4 mmol/l potassium solution	M/s Fresenius Medical Care India	FDC Division
23	Albumin	Dr. Kapil Dev, AIIMS	Biological (Blood Products)
24	Tenectaplastase	Genovve Biopharma	Biological (Recombinant)
25	Abciximab	Reliance Life Sciences	Biological (Recombinant)
26	Adalimumab	Reliance Life Sciences	Biological (Recombinant)
27	Recombinant Human Chorionic Gonadotrophin (r-hCG)	Bharat Serums & Vaccines	Biological (Recombinant)
28	Hydrochlorothiazide	IPCA Labs	SND
29	Guaifensin	Manipal Accunova	SND
30	Autologous Cultured Chondrocytes	Reliance Life Sciences	Biological (Stem Cells)
31	Autologous Myoblasts	Reliance Life Sciences	Biological (Stem Cells)
32	Allogenic Placental Derived Cells	ClinRx Labs.	Biological (Stem Cells)
33	Autologous Adipose Derives Adult Stem Cells (Idiopathic pulmonary fibrosis)	Kasiak Research	Biological (Stem Cells)
34	Autologous Adipose Derives Adult Stem Cells	Kasiak Research	Biological (Stem Cells)

The committee made following recommendations in respect of the above 34 proposals:

- For the proposals at Sr. No. 1, 2, 4, 5, 6, 12, 13, 14, 29, which are related to the clinical trial applications submitted by CROs, the committee recommended that following information should be obtained for review in the next meeting.
 1. Name of sponsors/manufacturer of the experimental drug.
 2. Financial status of these CROs in light of requirements as per the rules, for medical management and payment of compensation in case of injury/death in clinical trial.
- For the proposal at Sr. No. 18, which is related to clinical trial of platelet rich plasma (PRP), the committee recommended that details of the proposal as per the format should be forwarded to the members for further review, as the information forwarded was not adequate.

- For proposal at Sr. No. 23, which is related to clinical trial of albumin in hypoalbuminemic patients, the committee opined that how such patients in control group will receive placebo (0.9% sodium chloride solution) in place of albumin. All such hypoalbuminemic patients are required to be administered with albumin. Clarification/justification should be submitted to the committee for further review.
- The proposal at Sr. No. 27, the committee noted that NDAC has recommended that firm should increase the sample size and number of centers in the study. The action taken in this regards should be submitted to committee for further review.
- For proposals at Sr. No. 30, 31, 32, 33, 34, which are related to clinical trials of cell therapy, the committee noted that the Cellular Biology Based Therapeutic Drug Evaluation Committee (CBBTDEC) has given conditional recommendation/ sought clarification. Therefore, the Committee recommended that the actions taken on the recommendations of CBBTDEC should be submitted for further consideration.
- For remaining 17 proposals, the committee recommended for giving permission to conduct the clinical trial.

The meeting ended with the vote thanks to the chair.
