

MINUTES OF 15th MEETING OF THE TECHNICAL COMMITTEE HELD ON 04.06.2014 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. Nandini Kumar,
Former Dy. Director (Sr. Grade)
National Institute of Epidemiology,
ICMR, Delhi | Member |
| 3. | Dr. Ashok Kumar Das,
Director-Professor of Medicine & Medical
Superintendent, JIPMER, Puducherry. | Member |
| 4. | Dr. S.N. Gaur,
Prof. & Head, Dept. of Respiratory Medicine,
V.P. Chest Institute, New Delhi | Member |
| 5. | Dr. P.K. Dalal,
HOD, Dept. of Psychiatry,
KGMU Medical College, Lucknow. | Member |

From CDSCO:

1. Dr. G.N. Singh,
Drugs Controller General (India)
2. Dr. V.G. Somani
Joint Drugs Controller (India)
3. Sh. R. Chandrashekar
Deputy Drugs Controller (India)
4. Mrs. A. Visala
Deputy Drugs Controller (India)

1. **Proposals of Clinical Trials recommended by NDAC / IND but yet to be approved by CDSCO**

The Committee deliberated the 29 cases of various categories of clinical trials. These cases have already been recommended by the NDACs. The Committee has assessed these proposals based on NDAC's assessment and their own assessment of various scientific and ethical parameters of the proposal specially with respect to risk versus benefit to the patients, innovation *vis-a-vis* existing therapeutic option and unmet medical need in the country.

Out of these 29 cases, there were 21 cases of global clinical trials/ clinical trials of NCEs (12 cases of fresh proposal and 09 cases of re-deliberation in which there was no pharmacologist/ expert of the specific therapeutic area in the NDAC meetings), 08 cases were related to clinical trials for approval of New Drugs including fixed dose combination, subsequent new drugs and biologicals. Detailed information on these proposals as per the prescribed format was forwarded to the members through e-mail.

In compliance with the direction of the Hon'ble Supreme Court, the Committee evaluated 21 cases of global clinical trials/ clinical trials of NCEs in terms of the three parameters viz risk versus benefit to the patients, innovation *vis-a-vis* existing therapeutic option and unmet medical need in the country.

After deliberation, the Committee recommended for approval of clinical trials in 19 cases. In remaining 2 cases, the Committee has sought certain additional data/ information.

Details of these cases along with their evaluation in terms of the three parameters and recommendations of the Committee are mentioned in the **Annexure-I**.

Thereafter, the Committee evaluated the remaining 08 cases which were related to clinical trials for approval of New Drugs including fixed dose combination, subsequent new drugs and biologicals.

After deliberation, the Committee recommended for approval of clinical trials in all 8 cases.

The details of 08 cases alongwith the recommendations of the Committee is mentioned in the **Annexure-II**.

2. Requirement of Ethics Committees registration where there are less than 50 bedded hospitals.

In the 14th Technical Committee meeting it was reiterated that only those Multispecialty hospitals having minimum of 50 beds and having adequate emergency facility and institutional ethics Committee can be considered as trial sites.

The Committee noted that CDSCO has been registering Institutional ethics Committee for oversight on Clinical trials and independent EC's for oversight on BA-BE studies with old molecules. The Committee was appraised of the request from the ethics Committee based at OPD Clinics and nursing homes (having less than 50 bed strength) etc, seeking approval for oversight on clinical trials.

The Committee opined that only those sites that are having a minimum of 50 bed strength will be treated as clinical trial sites and accordingly such sites must have an institutional Ethics Committees, while Ethics Committee constituted by OPD clinics and nursing homes having less than 50 bed strength must be treated as Ethics Committee for oversight on BA-BE studies.

The meeting ended with the vote of thanks to the Chair.

Annexure-I

A. List of 21 cases of global clinical trials/ clinical trials of NCEs along with their evaluations and recommendations of the Technical Committee in its 15th Meeting.

Sr. No.	Drug	Applicant Name	Protocol No	Parameters 1. risk versus benefit to the patients 2. innovation vis-a-vis existing therapeutic option 3. unmet medical need in the country	Recommendations
1.	Herpes zoster gE recombinant protein adjuvanted with AS01B Adjuvant system	M/s GSK Pharma Ltd	Zoster-039 (116428)	<p>Risk versus benefit to the patients- The risk vs benefit profile of the test drug from various preclinical toxicity studies including single dose study as well as 28 days repeated dose toxicity study and phase I, IIa, III clinical studies justify the conduct of this Clinical Trial.</p> <p>Innovation vis-a-vis existing therapeutic option- Currently there is no vaccine for the prevention of HZ in immune compromised patients. The purpose of the study is to assess the safety and immunogenicity of candidate vaccine (test drug) in adults aged 18 years and older with hematologic malignancies.</p> <p>Unmet medical need in the country- Currently there is no vaccine for prophylaxis of HZ in immune compromised patients.</p>	<p>The Committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study</p> <p>((NDAC Recommendation: The Responses to the queries submitted by the company were reviewed and found satisfactory. Proposal recommended for approval. The study is to be conducted on 21 subjects in India</p>

2.	Apitox® [purified honeybee (Apismellifer a) venom]	M/s Spectrum Clinical Research Pvt. Ltd. Mumbai	01-13	<p>Risk versus benefit to the patients - Pk and phase II data in Indian subjects is required before the proposed phase III trial protocol is permitted.</p>	<p>The Committee evaluated and opined that Pk and phase II data in Indian subjects is required before the proposed phase III trial protocol is permitted.</p> <p>(NDAC Recommendation: The committee after due deliberation opined that data from phase I and phase II studies in Indian subjects is required before conduct of the proposed phase III. Further the Committee also opined that the drug Apitox per-se has had no substantial benefit over and above the existing therapies for OA, but is meant for palliative care only.</p>
				<p>Innovation vis-a-vis existing therapeutic options The existing therapeutic options for RA include DMARDs and monoclonal antibodies. Honey bee venom for RA may potentially be an innovative therapy. The purpose of the study is for Safety and Efficacy evaluation of test drug in Patients having Osteoarthritis of the Knee.</p>	
				<p>Unmet medical need in the country : Analgesics and steroids are associated with GI irritation, stomach ulceration and in some cases renal damage. Test drug may provide additional treatment options for RA.</p>	

3.	Meningococcal (Groups A, C, Y and W•135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (Menactra)	M/sSanofi Pasteur India Private Limited	MTA70	<p>Risk versus benefit to the patients- The risk vs benefit profile of the test drug from pharmacological toxicity, immunogenicity studies and clinical trials in the 2-55yrs age group justify the conduct of this study. The product is approved in India for the age group 2-55yrs and the proposed trial is in the lower age group</p> <p>Innovation vis-a-vis existing therapeutic option- The primary objective of the study is to assess the sero-protection rate after the second of the 02 doses of Menactra administered three to six months apart.</p> <p>Unmet medical need in the country- There is no licensed vaccine for the age group 9-23 months currently in India.</p>	<p>The Committee reviewed the proposal vis-a vis the prescribed parameters and recommended the conduct of the study in line with the NDAC recommendation.</p> <p>(NDAC Recommendation: The committee recommended the study with following stipulations: Two more sites from western and southern region of the countries shall be submitted to CDSCO for approval. For market authorization in India, data on an optimum number of subjects should be submitted separately to CDSCO for further review by NDAC.)</p>
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4.	PF-05280014 (Trastuzumab)	M/s Pfizer Ltd	B3271002	<p>Risk versus benefit to the patients- The risk versus benefit of the test drug from preclinical single dose, repeat dose toxicokinetic studies and Phase I and human immunogenicity study justify the conduct of this clinical trial</p> <p>Innovation vis-a-vis existing therapeutic option- Trastuzumab is a high end monoclonal antibody for treatment of HER2 positive MBC in conjunction with other chemotherapeutic agents</p> <p>The primary Objective of this study is to compare the objective response rate (ORR) in patients with metastatic HER2-positive breast cancer who receive trastuzumab-Pfizer to those who receive trastuzumab-EU in combination with paclitaxel.</p> <p>Unmet medical need in the country- Trastuzumab is a monoclonal antibody indicated for HER2 positive MBC. Availability of this drug from multisource will be in the interest of the nation.</p>	<p>The Committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study.</p> <p>(NDAC Recommendation: The committee examined and recommended for the conduct of the trial)</p>
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5.	INC424 (Ruxolitinib)	M/s Novartis Healthcare Private Limited	CINC424 B2401	<p>Risk versus benefit to the patients- The risk versus benefit of the test drug in various toxicity studies including single, repeat dose studies, genotoxicity, developmental toxicity as well as in various clinical studies-i.e. phase I,II and phase III (Specially in PV justify the conduct of this Phase IIIb study in polycythemia vera patients.</p> <p>Innovation existing vis-a-vis therapeutic option- Therapeutic options for Polycythemia Vera patients other than Hydroxuurea is limited. Patients who are resistant or intolerant to this drug may potentially benefit from the test drug. The purpose of the study is to compare the efficacy of ruxolitinib to best available therapy as assessed by Hct control at week 28.</p> <p>Unmet medical need in the country- There is an unmet need for well tolerated and efficacious therapies for the condition Polycythemia Vera.</p>	<p>The Committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study.</p> <p>(NDAC Recommendation: Ruxolitinib is a targeted therapy and there is no other therapy currently in this category for polycythemia vera other than hydroxyurea. Therefore this clinical trial meets the genuine unmet need condition. NDAC therefore recommends approval of the clinical trial.)</p>
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6.	BevacizumabBio-Similar (BEVZ92)	M/s Cliantha Research Ltd	BEVZ92-A-01-13	<p>Risk versus benefit to the patients- The risk versus benefit of the test drug from characterization assays, preclinical repeat dose and toxicokinetic studies in monkeys justify the conduct of the proposed clinical trial.</p> <p>Innovation vis-a-vis existing therapeutic option- This drug is a high end monoclonal antibody for the treatment of metastatic colorectal cancer and. The purpose of the study is to compare the pharmacokinetic (PK) and safety profile of BevacizumabBiosimilar (BEVZ92) in combination with FOLFOX or FOLFIRI versus innovators Bevacizumab in combination with FOLFOX or FOLFIRI.</p> <p>Unmet medical need in the country- Availability of Bevacizumab from multisource will benefit Indian patients in the management of metastatic colo-rectal cancer.</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study.</p> <p>(NDAC Recommendation: The NDAC after review of the protocol and the presentation made by the firm, opined that since this is a first time used in human subjects, the trial may be approved with a condition that the interim analysis for safety be submitted after first cohort of six patients. Further approval may be granted based on the above results.)</p>
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7.	Human cell line recombinant factor VIII	M/s Max Neeman Medical International Limited	GENA-05	<p>Risk versus benefit to the patients- The risk versus benefit of the test drug from safety and efficacy in pre-clinical, repeat dose toxicity and clinical study in Hemophilia A. justify the proposed clinical trial.</p> <p>Innovation vis-a-vis existing therapeutic option- Recombinant factor VIII concentrate may provide an alternate option to plasma derived factor VIII cryoprecipitate and FFP for severe haemophilia A treatment. The purpose of the study is to assess immunogenicity, efficacy safety and tolerability of the test drug in previously untreated severe haemophilia A patients (prophylaxis treatment).</p> <p>Unmet medical need in the country- Multisource availability of recombinant factor VIII in the country will benefit Indian patients.</p>	<p>The Committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study.</p> <p>(NDAC Recommendation: The NDAC has examined and opined that any patient who has inhibitor despite ITI, the firm will provide free medical management/standard care for a period of 03 years post completion of the trial, committee approved this amendment.)</p>
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8.	Bio-similar Rituximab	M/s PPD	GP13-301	<p>Risk versus benefit to the patients. The risk versus benefit of the test drug from the characterization, pre-clinical, comparative toxicokinetic studies, repeated dose toxicity and clinical trials to assess the comparative PK/PD with the innovator product justify the conduct of this phase III study.</p> <p>Innovation vis-a-vis existing therapeutic option- Rituximab is a high end monoclonal antibody/antineoplastic. The purpose of this study is to demonstrate comparability of ORR of the test drug with that of the innovator product in previously untreated advanced stage of FL patients.</p> <p>Unmet medical need in the country- Multisource availability of this high-end monoclonal antibody Rituximab In NHFL patients will help Indian patients.</p>	<p>The Committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study.</p> <p>(NDAC Recommendation: Follicular Lymphoma is a disease of older age and there is as no safety related issues in this age group, as observed from global data in the elderly i.e. above 65 years of age. Hence the NDAC recommends for age relaxation in India i.e. inclusion of subjects above 65 years of age and the protocol amendment -3.protocol amendment -3</p>
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9.	IB1001 (lyophilized recombinant factor IX)	M/s Max Neeman Medical International Limited,	IB1001-01	<p>Risk versus benefit to the patients-The risk versus benefit of the test drug from preclinical toxicity studies and in clinical study to evaluate PK and safety justify the conduct of this phase III study.</p> <p>Innovation vis-a-vis existing therapeutic option-</p> <p>The supply of human plasma derived factor IX may be a limiting factor for the availability of this substitution therapy. Multisource availability of this drug either as plasma derived or the recombinant factor IX may benefit Indian Patients.</p> <p>The purpose of the study is to evaluate the safety, Pharmacokinetics (PK) and efficacy of the test drug in prophylaxis and on-demand treatment groups of subjects with haemophilia B.</p> <p>Unmet medical need in the country –</p> <p>There is limited accessibility to this product which is indicated for prophylaxis and treatment of any bleeding and in surgery.</p>	<p>The Committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study.</p> <p>(NDAC Recommendation:</p> <p>The committee recommended the protocol amendment i.e. use of polished product for all the subjects in India.)</p>
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10.	Octafibrin (Human Plasma Derived Fibrinogen)	M/s Max Neeman Medical International Limited,	FORMA-01	<p>Risk versus benefit to the patients- The risk versus benefit of the test drug in preclinical pharmacology, toxicity studies justify the conduct of this study.</p> <p>Innovation vis-a-vis existing therapeutic option- Multisource availability of Human Plasma Derived Fibrinogen may benefit Indian subjects.</p> <p>Purpose of the study is to determine the PK, efficacy and safety of test drug (octafibrin) compared to innovator product in subjects with Congenital Fibrinogen Deficiency.</p> <p>Unmet medical need in the country-Currently available treatments include large volumes of plasma or cryoprecipitate for serious and emergency bleeds as well as in the management of surgical cases. Fibrinogen concentrates availability may help in decreasing the volumes to be infused in emergency and serious bleeds etc.</p>	<p>The Committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study.</p> <p>(NDAC Recommendation: The company provided the interim safety analysis report which was found be satisfactory. Since there was no safety issue, the committee recommended the inclusion of two subjects as sought by the firm.)</p>
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11.	SB3 (Trastuzumabbiosimilar)	M/s SIRO Clinpharm Pvt Ltd	SB3-G31-BC	<p>Risk versus benefit to the patients Based on the animal toxicity data including 4 weeks in-vivo repeated dose toxicity studies, the committee opined that the clinical trial data generated so far in the country of origin should be submitted before the proposed trial protocol can be permitted.</p> <p>Innovation vis-a-vis existing therapeutic option- Trastuzumab is a high-end monoclonal antibody. The purpose of the study is to demonstrate comparable clinical efficacy of the test drug with that of the innovator product in Her2 + MBC in neo- adjuvant setting.</p> <p>Unmet medical need in the country- Multisource availability of trastuzumab may benefit Indian patients.</p>	<p>The committee opined that the clinical trial data generated so far in the country of origin should be submitted before the proposed trial protocol can be permitted.</p> <p>(NDAC Recommendation: The NDAC examined and opined that the proposed trial may be approved as such.)</p>
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12.	Baricitinib (LY3009104)	M/s Eli Lilly and Company (India) Private Limited	I4V-MC- JADY	<p>Risk versus benefit to the patients- The risk versus benefit of test drug from safety and efficacy in pharmacological toxicological, toxico-kinetic studies and in several clinical phase I and II studies justify the conduct of this study.</p> <p>Innovation vis-a-vis existing therapeutic option- Baricitinib belongs to a new drug class that selectively inhibits JAKI and JAKII signaling pathways.</p> <p>The purpose of the study is to evaluate the long term safety and tolerability of baricitinib in patients who have completed a previous baricitinib RA study.</p> <p>Unmet medical need in the country - RA patients who fail on DMARDs and who may not wish to take biological (that are injectable) may have a wider option with this class of oral drugs</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study</p> <p>(NDAC Recommendation: The NDAC examined the proposal and recommended the conduct of this study i.e. the extended therapy with the drug in patients who had responded in the previous trials may be allowed subject to the condition that the extended Lipid profile monitoring shall be done every three months till the study ends)</p>
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13	<p>Glartus[®], Recomb inant Insulin Glargine Injection 100 IU/mL 21A- Gly- 30Ba-L- Arg- 30Bb-L- Arg- human insulin</p>	M/s Wockhar dt Ltd.	P3-GLR- IMSFDA-01	<p>Risk versus benefit to the patients- The risk versus benefit profile of the test drug (Recombinant Insulin Glargine) from animal toxicity data including repeated dose toxicokinetic studies and several clinical studies justify the conduct of the study.</p> <p>Innovation vis-a-vis existing therapeutic option- The purpose of the study is to compare the change in glycosylated haemoglobin (HbA1c), from baseline to 6 months of treatment, of patients in the Wockhardt's Glargine arm with patients in the Innovator product arm (as a surrogate indicator of change in the immunogenic response in both arms).</p> <p>Unmet medical need in the country- This comparative study of Glargine, (an Approved product in India)) with the innovator product will be in the interest of the Indian patients.</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study.</p> <p>(NDAC Recommendation : The committee has recommended for the said study with the current version 7 of protocol amendment</p>
14.	<p>Lyophilized plasma – derived Factor VIII (EMOC LOT)</p>	M/s Max Neeman	FCG-CNS- 001	<p>Risk versus benefit to the patients- This product is approved In India for replacement of the factor VIII in severe to moderate Haemophilia A patients.</p> <p>Innovation vis-a-vis existing therapeutic options: The study is to assess the immune tolerance induction in severe or moderate Hemophilia A patients with inhibitor induced by factor VIII concentrate containing VWF.</p> <p>Unmet medical need in the country- This is a Phase IV study to assess whether Factor VIII/VWF concentrate is able to induce safely immune tolerance in Hemophilia A patients with inhibitors. The assessment may benefit the Indian Patients.</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study</p> <p>(NDAC Recommendation: The committee recommended for the conduct of the phase IV study with the drug which is a plasma derived product in Hemophilia A patient. 50% of the sites shall be government hospitals.)</p>

15	Pasireotide dihydrochloride/ SOM 230	M/s Novartis	CSOM230G2 304	<p>Risk versus benefit to the patients- The risk versus benefit of the test drug from the various animal toxicity data including single dose, repeated dose and in several phase I, II, III clinical studies justify the conduct of this study.</p> <p>Innovation vis-a-vis existing therapeutic option- Pasireotide is a pituitary-targeted medical therapy directly aimed at the underlying mechanism of Cushing's disease. The purpose of the study is to assess the efficacy of two Pasireotide LAR regimen (starting dose of 10 mg and 30 mg independently in patients with Cushing's disease after 7 months of treatment regardless of up titration at month 4</p> <p>Unmet medical need in the country- Surgery is the first line of treatment for Cushing's disease but associated with high relapse. Currently there are no treatment options that target the underlying ACTH-Secreting pituitary Adenoma. Pasireotide provides a pituitary directed medical treatment targeting the underlying cause of the disease.</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study</p> <p>(NDAC Recommendation: The committee has recommended for this study.)</p>
16	Pertuzumab concentrate for solution for infusion in single dose vials [420mg-14ml/vial]	M/s Roche	MO28047(PE RUSE)	<p>Risk versus benefit to the patients- The risk versus benefit profile of the test drug in various animal toxicity data including single dose, repeated dose and in phase I, II, III clinical trial justify the conduct of the study.</p> <p>Innovation vis-a-vis existing therapeutic option- Trastuzumab and pertuzumab bind to distinct epitopes on the HER 2 receptors resulting in Augmented therapeutic efficacy. The purpose of the study is to characterize the safety and tolerability profile of the combination of the two anti HER2 antibodies Pertuzumab and Trastuzumab with taxanes in Indian patients.</p> <p>Unmet medical need in the country- More therapeutic options are</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study</p> <p>(NDAC Recommendation: The committee recommended for the conduct of the phase IIb protocol subject to the condition that 50% of the sites shall be government hospitals.)</p>

				needed for the first-line therapy of the HER2+ve metastatic breast cancer.	
17	Semaglutide	M/s Novo Nordisk	NN9535-3626	<p>Risk versus benefit to the patients- The risk versus benefit of the test drug in various animal toxicity studies including single dose, repeat dose and in phase I, II clinical trials justify the conduct of the study.</p> <p>Innovation vis-a-vis existing therapeutic option- The once weekly administration is expected to improve the treatment compliance significantly and further maintains the optimal glycemic levels.</p> <p>The purpose of the study is to compare the effect of once-weekly dosing of two dose levels of semaglutide versus sitagliptin 100 mg once daily after 56 weeks of treatment.</p> <p>Unmet medical need in the country- Sustained release options such as once weekly dosing compared to daily dosing of anti-diabetic drugs may ensure better patient compliance and glycemic control.</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study</p> <p>(NDAC Recommendation: The committee has recommended for the proposed trial subject to inclusion of DSMB. This is also subject to condition that those who have less than 18.5 kg /m² BMI will be excluded.)</p>
18	Liraglutide (Victoza®)	M/s Novo Nordisk	NN2211-4059	<p>Risk versus benefit to the patients-The risk versus benefit of the test drug from various preclinical, toxicity studies and clinical trials including phase III justify the conduct of this Phase IV clinical trial protocol.</p> <p>Innovation vis-a-vis existing therapeutic option- The purpose of this trial is to study the switch ability from metformin plus sitagliptine to metformin plus liraglutide for better glycemic control with associated reduction in body weight while still being on dual therapy in type 2 Diabetis.</p> <p>Unmet medical need in the country-Improved treatment regimen for patients who are having poor control of T2DM with existing medication.</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study.</p> <p>(NDAC Recommendation: he committee recommended for proposed trial subjects to inclusion of DSMB and the condition that those who have less than 18.5 kg/m² BMI will be excluded.)</p>

19	Trastuzumabemtansine for Injection	M/s Roche	MO28231 (KAMILLA)	<p>Risk versus benefit to the patients- The risk versus benefit of the test drug from various animal toxicity data including single dose, repeated dose and in phase I, II & III clinical trials justify the conduct of this Phase IIIb study.</p> <p>Innovation vis-a-vis existing therapeutic option- Trastuzumabemtansine is a novel antibody–drug conjugate (ADC) that is specifically designed for the treatment of HER2-positive malignancies. The purpose of the study is evaluate safety and tolerability of trastuzumabemtansine.</p> <p>Unmet medical need in the country- Targeted delivery system e.g. ADC agents for HER2 (+)vemBC may provide other treatment options.</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study</p> <p>(NDAC Recommendation: The committee recommended for the conduct of the phase III protocol subject to the condition that 50% of the sites shall be government hospitals.)</p>
20	LDK378	M/s Novartis	CLDK378A2301	<p>Risk versus benefit to the patients- The risk versus benefit of the test drug from various animal toxicity data including single dose, repeated dose and data of phase I, II & III clinical trials justify the conduct of the study.</p> <p>innovation vis-a-vis existing therapeutic option- LDK378 is a more potent and specific ALK inhibitor than currently available drugs of this class & also active against mutated versions of ALK</p> <p>unmet medical need in the country- The proposed trial may provide other / superior options for NSCLC. therapeutic</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study</p> <p>(NDAC Recommendation: The committee reviewed the protocol and presentation made and recommendation for the conduct of the conduct of the Phase III protocol subject to the condition that 50% of the sites shall be government hospitals.)</p>

21	Ifetroban Injection (thromboxane A2 / prostaglandin endoperoxide receptor (TPR) antagonist)	M/s Max Neeman	CPI-IFE-001	<p>Risk versus benefit to the patients- The risk vs. benefit of the test drug from various animal toxicity data including single dose, repeated dose and data of phase I and phase II clinical trials justify the conduct of the study.</p> <p>Innovation vis-a-vis existing therapeutic option- This test drug increases renal blood flow by selectively targeting the mediators involved in the pathophysiology of Hepato-renal Syndrome (HRS)</p> <p>The purpose of the study is to determine the pharmacokinetic profile & safety of ifetroban injection (multiple daily IV doses) in patients with HRS.</p> <p>Unmet medical need in the country- The treatment with ifetroban (test drug) may result in significantly improved renal function and survival rates with decreased liver transplant requirements in patients with HRS.</p>	<p>The committee evaluated the proposal against the prescribed parameters and concurred with NDAC opinion for the conduct of the study</p> <p>(NDAC Recommendation: The committee recommended proposed trial subject to exclusion of the female subjects.)</p>
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Annexure-II

B. List of 08 cases of clinical trial proposals other than GCT/NCE along with evaluations and recommendations of the Technical Committee in 15th Meeting.

SI No	Drug	Applicant Name	Protocol No	Recommendation
1.	Inactivated Trivalent Influenza Vaccine (Split Virion) I.P. Single dose	M/s Cadila Healthcare Ltd.,	INZT1001	Technical Committee evaluated and recommended for the conduct of clinical trial as per the submitted Clinical trial protocol.
2.	Varicella Vaccine (Live attenuated, Freeze Dried) I.P.- Single dose	M/s Cadila Healthcare Ltd.,	VRL1001 Version-1.2 Dated- 18-12-13	Technical Committee evaluated and recommended for the conduct of clinical trial as per the submitted Clinical trial protocol.
3.	Quadrivalent Inactivated Influenza Vaccine	M/s Sanofi Pasteur India Pvt Ltd	Q1V06	Technical Committee evaluated and recommended for the conduct of clinical trial as per the submitted Clinical trial protocol.
4.	DTwP-Hib vaccine (Easyfour-TT)	M/s Panacea Biotec Ltd.	PBL/CR/2013 /04/CT/EFTT	Technical Committee evaluated and recommended for the conduct of clinical trial as per the submitted Clinical trial protocol.
5.	Clonazepam	M/s IPCA Laboratories Ltd.	ID- IPCA/CZCR/ PIII-10	Technical Committee evaluated and recommended for the conduct of clinical trial as per the submitted Clinical trial protocol.

6.	Glimepiride, Metformin Hydrochloride Voglibose	M/s Sun Ltd.	SP\IP- 0701\0711	Technical Committee evaluated and recommended for the conduct of clinical trial as per the submitted Clinical trial protocol.
7.	Inactivated Tetravalent Influenza Vaccine (Split Virion)	M/s Cadila Healthcare Ltd.,	INZ1001	Technical Committee evaluated and recommended for the conduct of clinical trial as per the submitted Clinical trial protocol.
8.	AzilsartanM edoxomil	M/s SynokemPharma . Ltd.	Synokem/CT/ Azilsartan/10 2/010	The Committee noted that in the 14 th meeting it was recommended that the study in first 20 patients should be conducted in ICU setting. Based on results of 20 patients, the study can be extended on the subjects under OPD setting. Accordingly the firm has submitted the revised clinical trial protocol. After deliberation, the Committee evaluated and recommended for the conduct of the study.