Clinical Trails & Data Validation

1.1	Clinical Trials Studies Reimbursement APPLICATION FORM
1.2	DECLARATION by CEO/CHAIRMAN/MD/PARTNER/PROPRITER
2	AFFIDAVIT by CEO/CHAIRMAN/MD/PARTNER/PROPRITER
3	CA Certificate mentioning the particulars of Clinical study EXPENSES
4	EXPORT TURN OVER (FOB) & the TOTAL TURN OVER details of the company for the last three financial years duly attested by CA
5	DCGI approvals for Clinical trial Protocol & trail centers involved in conduct of studies *(Form CT-6 / NoC from DCGI)*along with Ethics Committee approvals
5.A	In case of Global Clinical Trail (GCT) wherein clinical studies areconducted in Overseas, approvals for the said study by concerned overseas Ethics Committee / respective National Regulatory Authority.
6	Registration of Clinical trials in the central registry i.e Clinical Trails registry India (CTRI) and Clinical Trails registry abroad if study is conducted aboard
7	Clinical Trials Report approved by the DCG(I)
7.A	In case of Global Clinical Trail (GCT), Clinical TrialReport approved by the respective National Regulatory Authority of countries where trails are executed
8	REGISTRATION CERTIFICATES/ Market Authorization of product for which Clinical Trials conducted (duly verified by Pharmexcil Office)
9	Approval of Clinical Trail Report by the foreign Regulatory Authority, based on which the subject Product is registered & Market Authorization is granted
10	Agreement of Sponsor with the Clinical Trail Site & Analytical Laboratory for data validation
11	Invoices raised by the Clinical Trials centers& Analytical laboratory for the conduct of clinical study & Data validation respectively
12	Bank Statement or Bank Transfer Remittance (SWIFT COPY) duly Attested by the Banker with employee code *(payment made by cash will not be accepted)*
13	Manufacturing License issued by State Drugs Controller/Licensing Authority for the subject product
14	Registration Guidelines, showing Clinical Trial studies requirements
15	Self-Attested Translation copies in English wherever necessary (ex: Invoice/Registration Certificates/Receipts/protocols/guidelines etc.)

List of Documents to be enclosed with MAI Application

Registration Certificate "Original + Copy"

a. Original Certificates need to be Verified/Attested by PHARMEXCIL Office (Hyderabad)
b. After Verification, the Originals will be returned back immediately

Note:

- **Financial year of the claim**, is considered basing on the**DATE OF ISSUE OF REGISTRATION CERTIFICATE**(Financial year period :**1st April** to **31st March**)
- Products **Registered indifferent Countries** need to be submitted in **different Applications**

- Products **pertaining to different Financial Years** to be submitted in **different Applications**
- **Eligibility Criteria:**Reference date to calculate 90 days for submission of claim application in MAI on-line portal is: Date of issue of the product registration certificate.
- Reimbursement under the scheme will be limited to the exporters having F.O.B. Value of Exports up-to Rs 100 crore during the preceding financial year.