



The partner
in your clinical trials
CRO/SMO

CLINICAL TRIALS - PHASE I TO IV

**DERMSCAN
GROUP**

Optimized Biometrics and Medical Writing Services

With its team of specialists, PharmaScan can provide you with the solutions most adapted to your Biostatistics, Data Management and Medical Writing projects.

Biostatistics

A team of biostatisticians provides its expertise along with the methodological advice necessary to write protocols and provides direct support in the final statistical development of your data.

Areas of Intervention

Methodology Consulting

- > Design of Experiments: parallel, crossover, latin-square.
- > Test of Hypotheses: comparative, equivalence, unilateral or bilateral trials.
- > Calculation of the number of required patients.
- > Randomization methods.

Write-up of the protocol statistical paragraph and/or detailed statistical analysis

Medical Data analysis with SAS® or SPSS®

- > According to the clinical test design.
- > Every phase of drug development (I to IV).
- > Intermediary, evaluation or exploratory analyses.

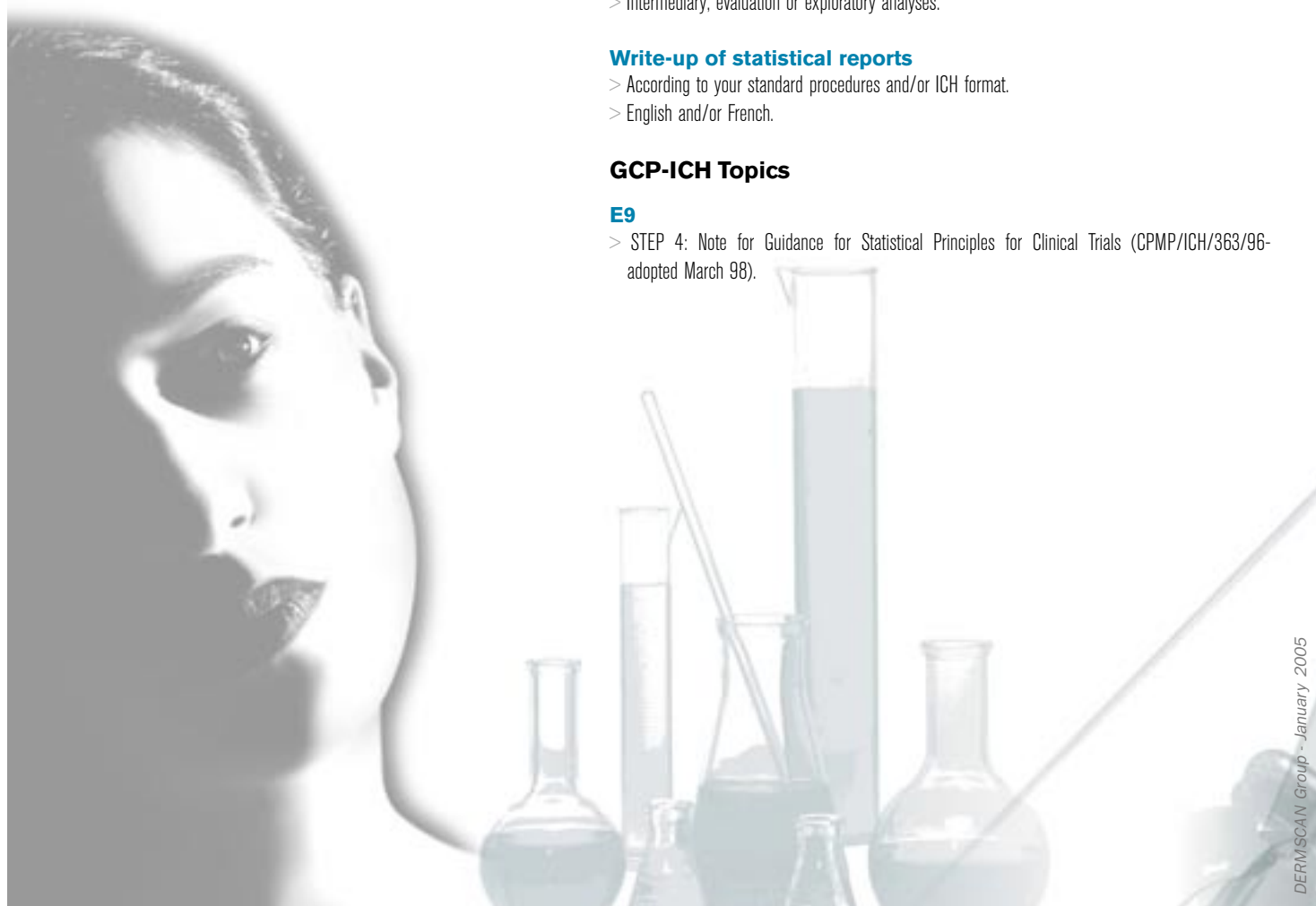
Write-up of statistical reports

- > According to your standard procedures and/or ICH format.
- > English and/or French.

GCP-ICH Topics

E9

- > STEP 4: Note for Guidance for Statistical Principles for Clinical Trials (CPMP/ICH/363/96-adopted March 98).



PharmaScan®

Data-Management

A team handles the set-up, supervision, validation and locking of data from your clinical studies.

Areas of Intervention

- > Casebook design in collaboration with CRAs and Biostatistics experts.
- > Casebook annotations according to CDISC recommendations or client specifications.
- > Data-Management Manual write-up.
- > Data base and data entry form design with the option to develop a library forms and labels customized to each sponsor.
- > Casebook reception and tracking.
- > Data double-entry.
- > Data trail audit.
- > Query management and resolution.
- > Masking of AE and medications.
- > Data Quality Control.
- > Frozen file.
- > Data base reconciliation.
- > Data export in SAS® or Excel format.
- > Verification for SAS® compatibility.

GCP-ICH Topics

ICH 2

- > ICH E2A, E2B, E2C, E2BM, etc.

Medical Writing

The write-up of the protocol and the publication of your results.

Areas of Intervention

- > Support in designing protocols.
- > Casebook, Patient information, Informed consent.
- > Write-up of clinical reports in ICH format.
- > Final reports (Phases I, II, III, IV).
- > Articles, Conferences, Scientific Posters, etc.

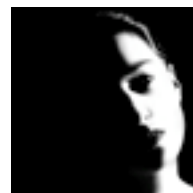
GCP-ICH Topics

E6

- > STEP 5: Note for guidance on Good Clinical Practice (CPMP/ICH/135/95 - adopted July 96).

E3

- > STEP 5: Note for guidance on Structure and Content of Clinical Study Reports Adopted by CPMP, December 95, issued as CPMP/ICH/137/95.



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