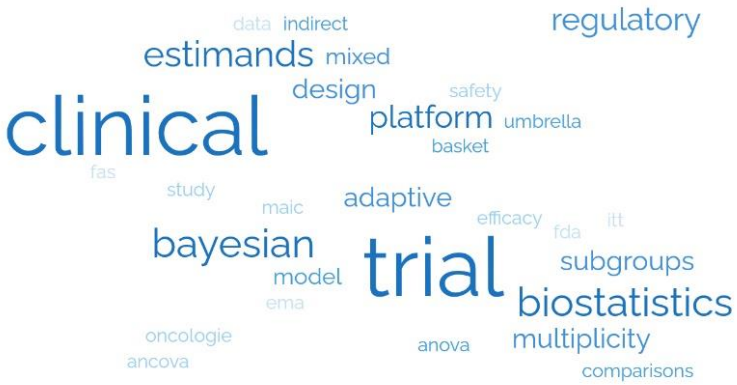

Training Catalog 2026

Data Management / Methodology and Statistics

eXYSTAT SAS with a capital of €15,000 Registered office: 4, rue Ernest Renan 92240 Malakoff - Approved Training Organization N°11922010092Telephone: 0981819392 – Mail: formation@exystat.com – Website: www.exystat.com

CATALOG 2026

DATA MANAGEMENT

1-2026
Clinical Data Management Fundamentals
From Data Collection to Regulatory Submission

2-2026
CDISC Standards Explained
A Practical Introduction to CDASH and SDTM

METHODOLOGY AND STATISTICS

3-2026
Introduction to Biostatistics and Methodology
Understanding Methods, Results and Limitations

4-2026
Regulatory Biostatistics
Statistical Requirements and Key EMA/FDA Guidelines

5-2026
Estimands in Clinical Trials (ICH E9 Addendum)
Theory, Interpretation and Practical Implementation

6-2026
Handling Missing Data and Multiple Imputations in Clinical Trials
Methodological Approaches and Regulatory Expectations

7-2026
Introduction to Bayesian Statistics
Foundations and Applications in Clinical Research

8-2026
Adaptive Methods in Clinical Trials for early development
Principles and Practical Considerations

9-2026
Adaptive Methods in Clinical Trials for late development
Principles and Practical Considerations

10-2026
Methodology of Phase I Oncology Clinical Trials
Designs and Dose-Escalation Approaches

11-2026
Survival Analysis in Clinical Studies (Level 1)
Key Methods and Interpretation

12-2026
Survival Analysis in Clinical Studies (Level 2)
Advanced Methods and Interpretation

13-2026
Indirect Comparisons in Clinical Trials
Methodological Principles and Applications in R and/or SAS

14-2026
Use of Historical and External Data in Clinical Trials
Methodological Approaches and Challenges

15-2026
Personalized Medicine in Clinical Trials
Subgroup Analyses and Biomarker-Driven Designs

16-2026
Quantitative Decision Making (QDM) in Drug Development
Statistical Frameworks and Applications

17-2026
Drug Benefit–Risk Assessment (BRA)
Statistical Methods and Regulatory Perspectives

18-2026
Multi-Regional Clinical Trials (MRCTs)
Design, Analysis and Regulatory Considerations

19-2026
Causal Inference in Clinical Trials
Concepts, Methods and Applications

20-2026
Mixed Linear Models for Clinical Research
Statistical Theory and Practical Applications in R and/or SAS

1-2026 Clinical Data Management Fundamentals
From Data Collection to Regulatory Submission

OBJECTIVES
Acquiring basics of Data Management process in clinical trials

TARGET AUDIENCE / PREREQUISITES

Project managers, CRAs, QA, students or staff working on clinical studies

DURATION / LOCATION

1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Generalities

- Objectives, evolutions and regulatory context

Data Management activities

- Planification/ set-up
- Data collection
- Data cleaning / Database structure with practical examples
- Database lock, archiving

Sponsor responsabilities
Quality and compliance
Tools and technologies
GDPR, Data security
Challenges and perspectives

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by data managers from eXYSTAT.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, julie.leboulicaut@exystat.com

2-2026 CDISC Standards Explained
A Practical Introduction to CDASH and SDTM

OBJECTIVES
Acquiring basics of CDISC standards in clinical trials

TARGET AUDIENCE / PREREQUISITES

Project managers, CRAs, QA, students or staff working on clinical studies

DURATION / LOCATION

1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

General Information
• History and objectives of CDISC, impact of CDISC on the evolution of Data Management
• Regulatory context
• CDISC website – Structure / How to find documentation
CDASH Format
• Concepts related to data collection format
• Principles and implementation
• Validation of CDASH documentation
SDTM Format
• Concepts related to the Data Management database format
• Principles and implementation of SAS-based mapping
• Validation of SDTM documentation
Define.xml
• Definition, key concepts, principles

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by data managers from eXYSTAT.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, julie.leboulicaut@exystat.com

3-2026 Introduction to Biostatistics and Methodology
Understanding Methods, Results and Limitations

OBJECTIVES

Gain a comprehensive yet accurate understanding of clinical trial methodology
Knowing the key issues and possible solutions during statistical analysis
Knowing how to quickly assess the methodological quality of a published article

TARGET AUDIENCE / PREREQUISITES

Clinical Project Managers, Researchers, Regulators, Medical Directors
General knowledge of clinical trials

DURATION / LOCATION

1 day (7 hours) / Paris, Lyon or in-house
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS

Registrations possible up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Introduction to Clinical Trials

- Presentation of the various reference documents (ICHE9, EMA Guidelines, FDA)
- Review of the content of key documents and processes: CRF, Blind-review report, SAP
- Why stats in clinical trials?

Review of the main methodological points

- Methodology of comparative superiority and non-inferiority trials, difference between the two, notion of 95%CI and role of the confidence interval versus p-value.
- Role and definition of populations (ITT, FAS, Per Protocol, Safety Set)

Calculating the number of patients – The power of a study

- How to define the assumptions needed to calculate a sample size
- Alpha risk, beta risk, calculation and understanding of the notion of power of a study

Review of the main statistical methods

- Presentation of the main statistical models and tests (t-test, chi2, Wilcoxon, logistic regression, ANCOVA, MMRM, Kaplan-Meyer model)
- Difference between a test and a model, introduction of covariates
- Awareness of the problems of missing data and multiplicity (why should we no longer use LOCF/ Why choose a main criterion? what about subgroup analyses)

Practical Application – Critical Review of Clinical Articles

1h30 of practical application to implement the knowledge acquired during the day
The articles can be chosen in relation to the interests of the participants (therapeutic areas, phases)

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, PDF of the presentation given at the beginning of the training. Alternation of theoretical and practical presentations, interactive exchanges between the participants and the trainer. The training will be provided by an experienced methodologist.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, m.dupuis@mdstatconsulting.fr

4-2026 Regulatory Biostatistics
Statistical Requirements and Key EMA/FDA Guidelines

OBJECTIVES
Acquire a good knowledge of international methodological guidelines to promote exchanges with agencies (FDA/EMA). To know the key issues and possible solutions during the statistical analysis of a pivotal study. Anticipate questions.

TARGET AUDIENCE / PREREQUISITES
CRO or biotech biostatisticians with a few years of experience

DURATION / LOCATION
1 day (7h) / intra-company only, minimum of 3 participants
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS
Registrations possible up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*
Choice of 3 workshops among the 5 below.

INTRODUCTION
- Background (pivotal dossiers, confirmatory trials, EMA/FDA)
- Presentation of the EMA website, where and how to find the methodology guidelines but also the guidelines specific to each therapeutic area

Workshop 1 – BASELINE COVARIATES
- Reference article 1 – "Subgroup analyses and other misuses of baseline data..."
- Discussions around the issue: baseline comparisons, choice of endpoints (raw value or change from baseline?), choice of covariates, stratification and link with randomization
- Guideline on Adjustment for Baseline Covariates (EMA-2015) – point-by-point review, discussion, consolidation/ Adjusting for covariates in RCTs (FDA-2021)

Workshop 2 – MULTIPLICITY
- Point to consider on Multiplicity issues (EMA-2002) – point-by-point review, discussion
- Presentation of the main adjustment methods, practical cases: Hierarchical method, Hochberg, Dunnett, FDR - Case of co-primary endpoints, case of secondary endpoints.
- Problem specific to interim analyses (adaptive designs)

Workshop 3 – MISSING DATA
- Problem of missing data – Recent developments, link with Estimands
- Guideline on missing data in confirmatory clinical trials (EMA-2010) – point-by-point review, discussion/NAS Report FDA (2010) - discussion - Examples of methods and interpretation, sensitivity analyses, Introduction to Tipping Point analysis..

Workshop 4 – INVESTIGATION OF SUBGROUPS
- Guideline on the investigation of subgroups in confirmatory clinical trials (EMA - 2019) – point-by-point review, discussion, consolidation
- Should we do analyses in subgroups? If so, which ones, for what purpose and how to present them?

Workshop 5 – ESTIMANDS
- Introduction to Estimands – Links and evolutions in relation to the guidelines discussed.
- Why and How to Use Estimands- Practical applications based on a synopsis. Defining Intercurrent Events / Knowing the 5 strategies for their consideration in the definition of an Estimand.

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES
Theoretical and practical approach, participatory and interactive method. PDF Training Material. The training will be provided by an experienced methodologist.

FOLLOW-UP AND EVALUATION
Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES
formation@exystat.com, m.dupuis@mdstatconsulting.fr

5-2026 Estimands in Clinical Trials (ICH E9 Addendum)
Theory, Interpretation and Practical Implementation

OBJECTIVES

Understanding the concept of estimands, its interest and its application
Being able to write a synopsis or a clinical study protocol using estimands
Knowing and anticipating regulatory expectations (EMA and FDA)

DURATION / LOCATION

1 day (7 hours) / Paris, Lyon or intra-company
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS

Registrations possible up to one week before the scheduled training date

TARGET AUDIENCE / PREREQUISITES

Clinical Project Managers – Biostatisticians – Other clinical trial specialists (data manager, regulatory, medical director) / General knowledge of phase 2-3 clinical trials

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Regulatory context

- Presentation of the various reference documents (ICHE9, EMA Guidelines, FDA)
- ICHE9 Add and estimand concept: Why this novelty?

State of the art Pre-Estimand

- Review of Population Definitions (FAS/PP) – Role, Interest, Limitations
- Data gaps: review of existing recommendations.
- Why the increasing complexity of methods has reached its limits and does not solve the problems

Estimands in theory

- Presentation of the content of the guideline (what is an estimand/how to define its 4 attributes) and identify and define Intercurrent events (ICEs)
- Strategies to deal with ICEs
- Role and definition of sensitivity analyses, difference in Multiple Imputation strategies
- Interest of the approach, examples of regulatory interactions and expectations

Estimands in practice – Working in small cross-functional subgroups

A specific time (at least 2h) for practical applications in small subgroups on synopses of real clinical studies will be planned to apply the guideline and open the discussions.

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, PDF of the presentation given at the beginning of the training. The feedback sessions will be an opportunity to exchange, ask questions, and dig into certain complicated points (for example, the management of intercurrent events).

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire. The training will be provided by an experienced methodologist.

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, m.dupuis@mdstatconsulting.fr

6-2026 Handling Missing Data and Multiple Imputations in Clinical Trials
Methodological Approaches and Regulatory Expectations

OBJECTIVES
Acquiring expertise in statistical techniques for dealing with missing data in clinical trials

TARGET AUDIENCE / PREREQUISITES
Statisticians in the field of clinical trials

DURATION / LOCATION
1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS
Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*
Types of missing data
- MCAR, MAR, MNAR

Imputation methods and sensitivity analyses
- Classical methods: (Modified) Complete-Case Analysis, Last Observation Carried Forward (LOCF), Worst Value Imputation, Unconditional/Conditional Mean Imputation
- Principles of Multiple Imputation: Joint Modelling (JM), Fully Conditional Specification (FCS)
- Rubin's rules

Regulatory guidelines
Practical examples and applications
- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES
Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION
Training certificate, satisfaction questionnaire.

CONTACT/REGISTRATIONS/FEES
formation@exystat.com, gaelle.saint-hilary@saryga.com

7-2026 Introduction to Bayesian Statistics
Foundations and Applications in Clinical Research

OBJECTIVES
Explore Bayesian statistics and learn how it differs from frequentist approaches
Build confidence in applying the key principles of Bayesian analysis

TARGET AUDIENCE/ PREREQUISITE

Statisticians in the field of clinical trials

DURATION/LOCATION

2 days / France (in-house or public training)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Introduction
- Bayesian thinking
- Bayesian vs Frequentist
- Probabilities: reminder

Prior Elicitation

Inference
- Bayes Factor
- Predictive Probability
- Credibility interval

MCMC Methods (Monte Carlo Markov Chains)
- Gibbs sampler
- Metropolis-Hasting algorithm
- Hamiltonian Monte Carlo

Practical examples and applications
- Using R or SAS

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by Laure Montané, Biostatistician and Methodologist.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, lmontane@oxalis-statconsulting.com

8-2026 Adaptive Methods in Clinical Trials for early development
Principles and Practical Considerations

OBJECTIVES

Gain the methodological foundations needed to understand and effectively apply adaptive methods for early stage trials.

TARGET AUDIENCE / PREREQUISITE

Statisticians in the field of clinical trials with experience using R

DURATION / LOCATION

1 day / France (in-house or public training)
Accessibility for persons with disabilities: contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Introduction
MCP-Mod (Multiple Comparisons Procedure - Modelling)
Design adaptations with/without type I error control

- Interim analysis for futility and/or efficacy
- Dose selection / multiple doses
- Incorporation of prior information through Bayesian framework
- Trial simulations

Case studies

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session. The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, lmontane@oxalis-statconsulting.com

9-2026 Adaptive Methods in Clinical Trials for late development
Principles and Practical Considerations

OBJECTIVES

Gain the methodological foundations needed to understand and effectively apply adaptive methods for late stage trials.

TARGET AUDIENCE / PREREQUISITE

Statisticians in the field of clinical trials with experience using R

DURATION / LOCATION

2 days / France (in-house or public training)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Each theory section will be followed by a practical session applying the concepts in R.

Introduction

- Definitions
- Guidelines
- Multiplicity

Common adaptive designs

- Group Sequential Designs
- Sample Size Reassessment
- Adaptive Enrichment designs
- Adaptive Randomization
- MAMS/Seamless

Case study

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by Laure Montané, Biostatistician and Methodologist.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, lmontane@oxalis-statconsulting.com

10-2026 Methodology of Phase I Oncology Clinical Trials
Designs and Dose-Escalation Approaches

OBJECTIVES

Understand the specific features of Phase I oncology trials and the associated methodologies in the context of FDA's Project Optimus

TARGET AUDIENCE / PREREQUISITE

Statisticians in the field of clinical trials, with basic knowledge of phase I trials

DURATION / LOCATION

1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Introduction

- Phase I, specificities and limitations in oncology
- Definitions: DLT, MTD, RP2D...

Single Agent Escalation Methods

- Rule based methods: 3+3, accelerated titration
- Model based methods: CRM, titeCRM, EWOC, BLRM
- Interval based methods: mTPI, keyboard, BOIN, i3+3
- Comparison of the methods and recommendations

Phase I-II designs

- MTD vs OBD
- Optimus project
- Efficacy/Toxicity Models
- Assisted designs : BOIN12, U-BOIN

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session. The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by Laure Montané, Biostatistician and Methodologist.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, lmontane@oxalis-statconsulting.com

11-2026 Survival Analysis in Clinical Studies (Level 1)
Key Methods and Interpretation

OBJECTIVES
Understand and use core survival analysis methods in clinical studies, with an emphasis on correct data handling and interpretation of results.

TARGET AUDIENCE/ PREREQUISITE
Statisticians in the field of clinical trials or epidemiology

DURATION/LOCATION
2 days / France (in-house or public training)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS
Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*
Efficacy criteria in oncology
Survival data
- Terminology
- Censoring
- Survival curve: Kaplan Meier's method
- Comparison of survival curves: Log-rank test
- Cox proportional hazard model
- Proportionality of risks and its consequences

Practical exercises with R or SAS

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES
Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by Laure Montané, Biostatistician and Methodologist.

FOLLOW-UP AND EVALUATION
Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES
formation@exystat.com, lmontane@oxalis-statconsulting.com

12-2026 Survival Analysis in Clinical Studies (Level 2)
Advanced Methods and Interpretation

OBJECTIVES
Understand unobserved heterogeneity and correlation in survival data
Identify situations where standard Cox models are inadequate

TARGET AUDIENCE/ PREREQUISITE

Statisticians in the field of clinical trials or epidemiology

DURATION/LOCATION

1 days (7 hours) / France (in-house or public training)
Accessibility for persons with disabilities: contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Part 1 – Frailty Models for Correlated Survival Data

- Sources of heterogeneity in survival data – Concept of frailty and random effects in survival analysis - Shared frailty models - Common frailty distributions (Gamma, Log-normal)
- Estimation and inference in frailty models (penalized likelihood, marginal likelihood, interpretation of variance components) - Model interpretation and practical implications

Part 2 – Extensions of Frailty Models

- Nested frailty models (e.g. patients within centers within regions)
- Multilevel and hierarchical frailty structures - Additive frailty models
- Comparison between multiplicative and additive frailty formulations

Part 3 – Joint Frailty Models for Recurrent Events and Terminal Events

- Recurrent event data: gap time vs calendar time formulations
- Informative censoring induced by terminal events
- Joint frailty models for recurrent events and terminal events
- Shared random effects and association structures
- Extensions using alternative count processes(e.g. Poisson, Negative Binomial processes)

Part 4 – Joint Models for Longitudinal Data and Time-to-Event Outcomes

- Longitudinal sub-models (linear mixed models)
- Survival sub-models with shared frailty/random effects
- Association structures between longitudinal trajectories and event risk
- Dynamic prediction of survival probabilities Individualized risk prediction and landmarking
- Model assessment and validation

Part 5 – Competing Risks Models

- Definition and examples of competing risks - Cause-specific hazard functions
- Cumulative incidence functions (CIF) - Relationship between hazards and incidence
    - Regression models for competing risks (Fine and Gray models)

Practical exercises with R or SAS

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session. The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by Laure Montané, Biostatistician and Methodologist.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, lmontane@oxalis-statconsulting.com

13-2026 Indirect Comparisons in Clinical Trials - *Methodological Principles and Applications in R and/or SAS*

OBJECTIVES

To know the theoretical basis of indirect comparisons and their applications and to know how to implement them on the R software (and/or SAS), and in particular:
- Understand the differences between indirect comparison methods.
- Know the most common functions in R/SAS to make indirect comparisons

TARGET AUDIENCE

Statisticians, students or staff working on statistical studies

PREREQUISITE

Good foundation in statistics and epidemiology, proficiency in propensity scores and basic statistical tests. Regular use of statistical software (R or SAS)

DURATION / LOCATION

1 day in person (7h) / eXYSTAT, 4 rue Ernest Renan 92240 MALAKOFF
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS

Registrations possible up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Each theoretical part will be followed by a practical part of the application of the theory under R or SAS. The R software and the Rstudio interface are used for importing, manipulating data, and writing models. The corresponding orders under SAS will be mentioned.

Definition of Indirect Comparisons:

- Direct, indirect or mixed comparison
- Form of indirect comparisons (anchored unanchored)
- Propensity Score and ESS
- Meta Analysis (Principle and Application)

Network meta-analysis (NMA)

- General idea
- Classification of NMAs
- Steps to follow and presentation of the results
- Hypothesis Testing
- Published Examples and Exercises

Matching adjustment indirect comparison (MAIC)

- General idea
- Population reweighting and estimation
- Published Examples and Exercises

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Theoretical and practical approach, participatory and interactive method. PDF Training Material.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, francois.montestruc@exystat.com

14-2026 Use of Historical and External Data in Clinical Trials
Methodological Approaches and Challenges

OBJECTIVES

Acquiring expertise in methodologies for integrating historical or external data into clinical trials in a robust manner, and learn from examples of their application in practice

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials. Knowledge of Bayesian statistics is desirable.

DURATION / LOCATION

2 days / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

General principles of historical / external data borrowing
Dynamic Bayesian borrowing approaches

- Meta-analytic predictive (MAP) model
- Robustification for dynamic borrowing
- Design planning, operating characteristics, and final analysis

Propensity score methods

- Estimate the propensity score
- Matching methods
- Weighting methods

Regulatory perspective
Practical examples and applications

- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, gaelle.saint-hilary@saryga.com

15-2026 Personalized Medicine in Clinical Trials
Subgroup Analyses and Biomarker-Driven Designs

OBJECTIVES

Acquiring expertise in statistical methods and trial designs for subgroup detection and the implementation of biomarker-driven clinical trials

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials

DURATION / LOCATION

2 days / France (in-house or public trainings)

Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Subgroup identification

- Predefined vs adaptive cutoffs
- Continuous vs categorical biomarkers
- Statistical methods for cutoff selection and subgroup identification (e.g. SIDES)
- Treatment effect estimation
- Sample size considerations

Trial design strategies

- Based on the stage of the development
- Based on the level of confidence in the biomarker

Regulatory perspective

Practical examples and applications

- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session. The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.

The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, gaelle.saint-hilary@saryga.com

16-2026 Quantitative Decision Making (QDM) in Drug Development / *Statistical Frameworks and Applications*

OBJECTIVES

Acquiring expertise in statistical methods for evidence-based decision-making in clinical development

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials

DURATION / LOCATION

2 days / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Probabilities of Success

- Posterior Probability of Success
- Predictive Probability of Success aka Assurance

Expert elicitation

- Overview of different approaches
- Focus on the Sheffield Elicitation Framework (SHELF)

Quantitative decision-making frameworks (Go / No-Go / Consider)

- Hypothesis testing and QDM framework
- One criterion, three outcomes QDM frameworks
- Two criteria, three outcomes QDM frameworks
- Operating characteristics
- More complex settings

Practical examples and applications

- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, gaelle.saint-hilary@saryga.com

17-2026 Drug Benefit–Risk Assessment (BRA)
Statistical Methods and Regulatory Perspectives

OBJECTIVES
Acquiring expertise in methodologies for evaluating benefit-risk trade-offs in drug development

TARGET AUDIENCE / PREREQUISITES
Statisticians in the field of clinical trials

DURATION / LOCATION
1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS
Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*
Qualitative assessment: structured frameworks for drug benefit-risk assessment
- Define key Benefits and Risks
- Summary of treatment performance for each criterion

Quantitative approaches
- Standardization of performance across criteria on a common scale
- Integration of criterion importance through weighting
- Multi-Criteria Decision Analysis (MCDA)
    - Linear or non-linear model
    - Consideration of uncertainty in the assessment

Operational considerations
Practical examples and applications
- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES
Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION
Training certificate, satisfaction questionnaire.

CONTACT/REGISTRATIONS/FEES
formation@exystat.com, gaelle.saint-hilary@saryga.com

18-2026 Multi-Regional Clinical Trials (MRCTs)
Design, Analysis and Regulatory Considerations

OBJECTIVES
Overview of the statistical and regulatory considerations involved in the design and analysis of Multi-Regional Clinical Trials (MRCTs)

TARGET AUDIENCE / PREREQUISITES
Statisticians in the field of clinical trials

DURATION / LOCATION
1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS
Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*
Regulatory guidelines and requirements
Models and sample size considerations
Quantifying regional treatment effects
Assessing consistency of treatments effects
- Shrinkage estimators, local consistency assessments

Special case of treatment effect consistency and sample size calculation for Japanese patients in MRCTs (PMDA requirements)
Practical examples and applications
- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES
Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION
Training certificate, satisfaction questionnaire.

CONTACT/REGISTRATIONS/FEES
formation@exystat.com, gaelle.saint-hilary@saryga.com

19-2026 Causal Inference in Clinical Trials

Concepts, Methods and Applications

OBJECTIVES

Acquiring basics of causal inference, emphasizing the distinction between correlation and causation in clinical trials

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials

DURATION / LOCATION

2 days / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Potential outcomes framework

- Definition of causal effects based on counterfactual reasoning
- Individual Treatment Effects (ITE) and Average Treatment Effects (ATE)

Assignment mechanisms

- The role of treatment assignment in causal inference
- Randomization, probabilistic assignment, and unconfoundedness

Causal diagrams

- To identify confounding and biases

Propensity score methods, instrumental variables

Estimands and causal inference

- Defining treatment effects appropriately within the potential outcomes framework

Regulatory perspective

Practical examples and applications

- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT/REGISTRATIONS/FEES

formation@exystat.com, gaelle.saint-hilary@saryga.com

20-2026 Mixed Linear Models for Clinical Research
Statistical Theory and Practical Applications in R and/or SAS

OBJECTIVES
Know the theoretical basis of mixed models and know how to implement it on the R software (and/or SAS), and in particular:
- Understand the differences between a fixed-effects model and a random-effects or mixed-effects model, know how to choose a model adapted to your data.

TARGET AUDIENCE
Statisticians, students or staff working on statistical studies

PREREQUISITE
Good basics in statistics, mastery of linear models, ANOVA, ANCOVA, and basic statistical tests. Regular use of statistical software (R preferred)

DURATION/LOCATION
2 days in person (2 pm) / eXYSTAT, 4 rue Ernest Renan 92240 MALAKOFF
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS
Registrations possible up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*
Each theoretical part will be followed by a practical part of applying the theory under R. The R software and the Rstudio interface are used for importing, manipulating data, and writing models. The corresponding orders under SAS will be discussed

Reminders about linear models with fixed effects:
- Linear models: linear regression, ANOVA, ANCOVA,
- Generalized linear models

Linear mixed models
- Theoretical presentation of the model (matrix writing, parameter estimation methods) and examples. Interpretation of the parameters of the mixed model.
- Selection of variables in the mixed model, comparison of several fixed-effect and/or random-effect models.
- Analysis of longitudinal or "repeated-measures" data: contribution of mixed models, different covariance structures
- Hierarchical or multi-level data analysis: hierarchical effect models

Mixed nonlinear models
- Extension to generalized models
- Model constructions and interpretation of mixed model parameters
- Commands and interpretation in R

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES
Classroom training session, PDF of the presentation given at the end of the training. Alternation of theoretical and practical presentations, interactive exchanges between the participants and the trainer.

FOLLOW-UP AND EVALUATION
Training certificate, satisfaction questionnaire

CONTACT/REGISTRATIONS/FEES
formation@exystat.com

REFERENCES

Maëva Dupuis created MDSTAT Consulting in 2011. Maeva is regularly called upon to supervise statistical analyses as a biostatistician-consultant/methodologist for the clinical development of new drug candidates, including protocol development, representation in regulatory statistics to agencies, statistical modeling, reporting across a wide range of therapeutic areas. Prior to founding MDSTAT, Maëva was Head of Statistics at SOLADIS and Thériamis, and held a position as Senior Statistician in Clinical Development at SANOFI-AVENTIS. Maëva has represented her clients several times at meetings with the FDA, the EMA and local European agencies, and regularly participates in Data Monitoring Committees (DMCs), as a methodologist for adaptive trials. Within MDSTAT, she is a consultant for many Biotechs and has been regularly leading training courses for more than 10 years, for both statisticians and non-statisticians, about regulatory clinical statistics. Maeva holded a position of Director, Biostatistics, at ALEXION (Astra Zeneca Rare Diseases) in Barcelona from 2022 to 2025.
She was elected as a member of the executive committee, responsible for training, in the Biopharmacy section of the French Statistical Society from 2005 to 2012.

maeva@mdstatconsulting.fr

Laure Montané is a biostatistician and methodologist in the field of clinical trials, she has worked for more than 13 years in structures of varying sizes: pharmaceutical laboratories, French healthcare establishments and CRO. After graduating as an engineer in mathematics and scientific computing, she joined Soladis and carried out statistical consulting for various clients including Sanofi, Pasteur, L'Oréal and Servier. She then took over the management of the preclinical biostatistics department at Servier and provided methodological support for in vitro and in vivo studies. She then held a position as a biostatistician and senior methodologist at the Léon Bérard Center where she was involved in phase I to III trials and was a member of the statistical committee of the GINECO group. She created Oxalis in 2021 and brings to her clients (Biotechs, CROs) an expertise that calls for in-depth knowledge of complex methods, including adaptive designs, multiplicity problems and the Bayesian approach. She regularly participates in DMCs as a voting member or as an independent statistician. Her skills allow her to cover many therapeutic areas with strong experience in oncology, and to intervene at all stages of drug development, from the preclinical phases to phase III.

lmontane@oxalis-statconsulting.com

François Montestruc has expertise in methodology, statistics and data-management of clinical studies. François has been working in the health industry for more than 25 years and has built a Biometrics department within Roche and then an epidemiological studies department. He was involved in all of Roche France's epidemiological studies until 2008. From 2008 to 2013, he joined a biotechnology company and again built the Biometrics department of a parent company and thus expanded his skills in the development of molecules in many indications. These two experiences led him to create eXYSTAT in 2013 to share his expertise with all healthcare stakeholders.
François also has an in-depth knowledge of the ANSM, MHRA, BfArM, Transparency Commission, EMA and FDA regulatory processes, having participated in numerous "scientific advices" or in the constitution of marketing authorization dossiers.
Finally, his expertise has led him to teach university courses, particularly in survival analysis, epidemiology or probabilities and to participate in the creation of the professional degree in "Statistics and Health" at the University of Paris V. He is a speaker at numerous training courses and seminars, for example at the Institut Pasteur, the University of Geneva, the ESIEE engineering school and at statistical congresses. Advising on the design of new clinical trials has remained passionately unchanged since the beginning of his career.

francois.montestruc@exystat.com

Gaëlle Saint-Hilary is a statistical methodologist and the founder and CEO of Saryga, a consultancy dedicated to supporting innovation in healthcare through advanced statistical methodologies and data-driven decision-making. With 20 years of experience in the pharmaceutical industry – including leadership and scientific roles at Servier and Novartis – she has established herself as a recognized expert in Bayesian statistics, quantitative decision-making, and benefit-risk assessment.

Gaëlle has led methodological innovations across all stages of drug development, from early-phase design and dose-finding to portfolio-level decision-making. Her expertise spans adaptive designs, historical data integration, biomarkers, and the development of quantitative tools to improve the success and efficiency of clinical programs. She has also served as an expert on advisory boards, steering committees and to support regulatory submissions.

Holding a Master in Biostatistics from ENSAI and a PhD in Mathematics from the Polytechnic University of Turin, Gaëlle has authored numerous peer-reviewed publications and regularly contributes to academic and industry conferences. Her company Saryga provides consultancy, training, and strategic support to pharmaceutical companies and biotechnology companies, while maintaining strong collaborations with academic researchers and international consortia.

gaelle.saint-hilary@saryga.com

Julie Le Boulicaut is CEO of eXYSTAT and a data manager with over 20 years of experience in the pharmaceutical and biotechnology industries. Before co-founding eXYSTAT, she held data management positions in both big pharma and biotech companies, where she led clinical data activities across various therapeutic areas. These roles allowed her to develop strong expertise in clinical data, regulatory compliance, and cross-functional collaboration.

She has worked on numerous clinical and epidemiological studies, with a particular focus on data quality and the implementation of CDISC standards (CDASH, SDTM and ADaM) to support regulatory submissions to authorities. At eXYSTAT, she now leads data management operations and helps sponsors improve the structure, reliability, and value of their clinical data. Julie also contributes to training initiatives, sharing her practical experience in data management processes.

julie.leboulicaut@exystat.com