Original questions of the survey in in English translation

1) Do you currently work or have you been working as biometrician/statistician in a medical ethics commission?

- yes
- no

2) In which kinds of medical ethic committees have you been working?

- medical ethic committee of a medical faculty of a university
- medical ethic committee of a State Chamber of Physicians (Landesärztekammer)
- others

3) Which German federal state is the medical ethics committees located to which you were affiliated?

- Baden-Württemberg
- Bavaria
- Berlin
- Brandenburg
- Bremen
- Hamburg
- Hesse
- Mecklenburg Western Pomerania
- Lower Saxony
- Northrhine - Westphalia
- Rhineland Palatinate
- Saarland
- Saxony - Anhalt
- Schleswig Holstein
- Thuringia
- Saxony

4) How many study proposals (amendments and annual reports excluded) do you review on average per year?

- up to 50
- 51 - 100
- 101 - 150
- 151 - 200
- more than 200

5) Which kinds of studies do you review as member of a medical ethics committee?

- Studies regulated by AMG (German Drug Act) or MPG (German Medical Products Act)
- Studies in a non-regulated setting
- Both

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6) Do you in general have the impression that the biostatistical quality of ethical proposals for studies regulated by AMG/MPG differs compared to proposals in a non-regulated setting?

- Yes, ethical proposals for studies regulated by AMG/MPG have a higher biostatistical quality on average
- Yes, ethical proposals for studies in a non-regulated setting have a higher biostatistical quality on average
- No, the biostatistical quality does not differ on average
- Not specified

7) Please complete the following statements related to biostatistical problems in ethical proposals for studies regulated by AMG/MPG through specification of approximate percentages according to your subjective assessment.

Part 1

- In x[%] of the ethical proposals, wording of study aims, hypotheses and/or endpoints are inadequate or inconsistent.
- In x[%] of the ethical proposals, specification of the significance level is missing.
- In x[%] of the ethical proposals, sample size calculation is incomplete, inadequate or missing completely.
- In x[%] of the ethical proposals, only general statements on statistical analysis methods are provided not fitting and addressing the specific study aim.
- In x[%] of the ethical proposals, no clear differentiation between confirmatory and explanatory analyses is provided.
- In x[%] of the ethical proposals, specification of one- or two-sided statistical testing is missing.

8) Part 2

- In x[%] of the ethical proposals, description of how to handle missing values is incomplete, inadequate or missing completely.
- In x[%] of the ethical proposals, description of how to handle multiple comparisons problems is incomplete, inadequate or missing completely.
- In x[%] of the ethical proposals, description of how and for which covariables adjustment is planned is incomplete, inadequate or missing completely.
- In x[%] of the ethical proposals, specification of randomization and stratification is incomplete, inadequate or missing completely.
- In x[%] of the ethical proposals no study biometrician is named.
- In x[%] of the ethical proposals, description of statistical methods is not sufficiently specified.

9) Please complete the following statements related to biostatistical problems in ethical proposals for non-regulated studies through specification of approximate percentages according to your subjective assessment.

Part 1

- In x[%] of the ethical proposals, wording of study aims, hypotheses and/or endpoints are inadequate or inconsistent.
- In x[%] of the ethical proposals, specification of the significance level is missing.
- In x[%] of the ethical proposals, sample size calculation is incomplete, inadequate or missing completely.
- In x[%] of the ethical proposals, only general statements on statistical analysis methods are provided not fitting and addressing the specific study aim.

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- In x[%] of the ethical proposals, no clear differentiation between confirmatory and explanatory analyses is provided.
- In x[%] of the ethical proposals, specification of one- or two-sided statistical testing is missing.

10) Part 2

- In x[%] of the ethical proposals, description of how to handle multiple comparisons problems is incomplete, inadequate or missing completely.
- In x[%] of the ethical proposals, description of how and for which covariables adjustment is planned is incomplete, inadequate or missing completely.
- In x[%] of the ethical proposals, specification of randomization and stratification is incomplete, inadequate or missing completely.
- In x[%] of the ethical proposals no study biometrician is named.
- In x[%] of the ethical proposals, description of statistical methods is not sufficiently specified.

11) How do you consider the need for additional training in the following biostatistical areas for investigators submitting protocols to medical ethics committees? (low, middle, high, not assessable)

- Study design
- Wording of the study aims, hypotheses and/or endpoints
- Sample size calculation
- Differentiation between confirmatory and exploratory analyses
- Handling of missing values
- Description of the statistical analysis
- Multiple comparisons problems
- Adjustment for covariables
- Randomization/stratification

12) Did you enjoyed our survey?

- yes
- no

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