621 Real World Study

STUDY ID

CT LUCIA 621P-BER-401-21

STATISTICAL ANALYIS PLAN

Version 1

20-Apr-2023

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ZEISS classification: Restricted

Statistical Analysis Plan

Basic study information:

Study Title	An open single-arm clinical investigation to evaluate the clinical safety and effectiveness of CT LUCIA 621P indicated for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataracts
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Study protocol version number / version date	Ver 1.0 / 20220831
Statistical analysis plan version number / version date	V1.0 / 2023-04-20
Investigational site	Hainan Boao [redacted] Aier Eye Hospital
Registrant	Carl Zeiss Meditec AG [redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Statistical analysis unit: [redacted] MedTech Co Ltd.

[redacted]

Approval page

Statistical analysis plan formulation and revision:

Statistical Analysis Plan No.	Version No. / Date	Revised history
SAP-CARL-2023-007	V1.0/2023-04-20	Initial release

[redacted]

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[redacted]



[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

1 Summary

This statistical analysis plan describes the implementation plan for the statistical analysis of an “An open single-arm clinical investigation to evaluate the clinical safety and effectiveness of CT LUCIA 621P indicated for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataracts”.

2 Purpose

To evaluate the clinical safety and effectiveness of CT LUCIA 621P indicated for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataracts.

3 Investigation Design

This clinical investigation is designed as an open, single arm study.

Hainan Boao Lecheng Aier Eye Hospital was selected as the investigational site to conduct this clinical study. After informed consent is signed by the patients and satisfying selection criteria, the patients will be included in the clinical investigation.

[redacted] this investigation focused on assessing the impact of optical design differences on the product's overall six-month postoperative efficiency. All subjects will be followed up preoperatively, intraoperatively, post-op 1 day, post-op 1 week ± 1 day, post-op 1 month ± 7 days, post-op 3 months ± 14 days, and post-op 6 months ± 30 days.

4 Sample Size

[redacted] the non-inferiority margin should not be lower than 10%, and the expected target rate for of the investigational device can be set at 82.5%.

[redacted]



It is calculated that at least 94 patients are required, taking into account a 10% dropout rate, a total of at least 105 patients will be required for this clinical investigation.

5 Evaluation Indicators

5.1 Primary effectiveness evaluation indicator

- **Evaluation indicator: Product efficiency at 6 months after implantation**
- Evaluation method: Monocular CDVA≥4.7 (≤0.3 logMAR) at 6 months after surgery was considered effective, and the effective rate was not less than 82.5% of the target value.

[redacted]

5.3 Safety evaluation

(1) Type, incidence and frequency (number of events) of postoperative cornea-related complications, such as corneal edema and corneal folds in study eyes.

Evaluation time and method: Cornea-related complications of study eyes at postoperative 1 day, 1 week ± 1 day, 1 month ± 7 days, 3 months ± 14 days and 6 months ± 30 days are recorded according to the slit lamp microscope results. [redacted]

[redacted]

(2) Corneal endothelial cell count: Corneal endothelial cell counts in study eyes at postoperative.

Evaluation time and method: Corneal endothelial cell counts in study eyes are measured with a corneal endothelial cell counter and recorded at postoperative 3 months ± 14 days and 6 months ± 30 days;

(3) Anterior and posterior segment inflammations: Type, incidence and frequency (number of events) of anterior and posterior segment inflammations in study eyes at postoperative visits, such as buoyant cells of anterior chamber, aqueous flare, hypopyon and the performance of endophthalmitis;

Evaluation time and method: Anterior and posterior segment inflammations in study eyes are measured according to slit lamp microscope results at postoperative 1 day, 1 week ± 1 day, 1 month ± 7 days, 3 months ± 14 days and 6 months ± 30 days. The aqueous flare found is graded according to the table below:

Table 2: Aqueous flare grading



(4) Fundus complications: Type, incidence and frequency (number of events) of fundus complications such as macular edema and retinal detachment in study eyes at postoperative visits;

Evaluation time and method: Fundus complications in study eyes are checked, recorded and reported at postoperative 1 day, 1 week ± 1 day, 1 month ± 7 days, 3 months ± 14 days and 6 months ± 30 days (with slit lamp microscope), 1 month (OCT test);

(5) Intraocular pressure: Intraocular pressure in study eyes at postoperative visits;

Evaluation time and method: Intraocular pressure in study eyes at postoperative 1 day, 1 week ± 1 day, 1 month ± 7 days, 3 months ± 14 days and 6 months ± 30 days are tested and recorded;

(6) Posterior capsular opacification and Nd:YAG capsulotomy: Incidence and frequency (number of events) of posterior capsular opacification and Nd:YAG in study eyes at postoperative visits;

Evaluation time and method: The condition of posterior capsular opacification in study eyes recorded and reported according to slit lamp microscope results, and Nd:YAG laser posterior capsulotomy is recorded and reported at postoperative 1 month ± 7 days, 3 months ± 14 days and 6 months ± 30 days .



(7) Intraocular lens status: Type, incidence and frequency (number of events) of IOL decentration, tilt, rotation, dislocation, opacity, etc, in study eyes at postoperative visits;

Evaluation time and method: IOL decentration, tilt, rotation, dislocation, opacity, etc, in study eyes at postoperative 1 day, 1 week ± 1 day, 1 month ± 7 days, 3 months ± 14 days and 6 months ± 30 days are recorded according to slit lamp microscope results;

(8) Secondary Surgical Intervention: Incidence of secondary surgical intervention in study eyes at postoperative visits.

Evaluation time and method: Cause, time, type and results of secondary surgical intervention in study eyes during the clinical trial are recorded;

(9) Adverse events and serious adverse events: Type, incidence and frequency (number of events) of adverse events and serious adverse events during the clinical trial.

Evaluation time and method: Adverse events and serious adverse events during the clinical trial are recorded.

(10) Device deficiency: Type, incidence and frequency (number of events) of device deficiency during the clinical trial.

Evaluation time and method: Type and time of device deficiency during the clinical trial are recorded;

[redacted]

6 Analysis Set

Statistical analysis will be carried out on the basis of the following analysis groups, and the analysis groups need to be clearly defined before the statistical analysis starts. The analysis groups in this study include:

(1) Full Analysis Set (FAS): It refers to a set of subjects determined on the basis of the Intention to Treat principle. It is the data set that includes all the subjects have used the study products.

(2) Per Protocol Set (PPS): It refers to a subgroup of the subjects who complete the trial without serious protocol deviations (such as violation of inclusion criteria or exclusion criteria and loss to follow-up).

(3) Safety set (SS): It is defined with the same method as FAS. Therefore, SS is not separately defined in the analysis.

Analysis of primary efficacy endpoints will be performed based on the basis of FAS and PPS simultaneously; in addition, analysis of all the baseline demographic information and secondary efficacy endpoints will be performed on the basis of FAS; safety evaluation is also performed on the basis of FAS.

7 Missing Data and Abnormal Value Handling

For the subjects who are not followed up or dropped out midway, when the efficacy results will be analyzed by the full analysis set (FAS), the missing values will be filled in by the Last Observation Carried Forward (LOCF) method. If there is no basis for filling, fill according to the worst filling method (i.e., treat as treatment failure).

8 Statistical Analysis

8.1 Statistical analysis software and basic principles

The Statistical analysis is performed using SAS® 9.4 statistical software (or higher). Efficacy indicators will be analyzed for both the full analysis data set and the per-protocol data set, safety indicators were analyzed for the safety data set. All statistical tests will be performed using two-sided tests, and P values less than or equal to 0.05 will be considered statistically significant for the differences tested (except as noted).

This study is a one-arm design, mainly based on descriptive statistical analysis. The description of quantitative indicators will calculate the mean, standard deviation, median, minimum and maximum, lower quartile (Q1) and upper quartile (Q3), and classification indicators will describe the number of cases and percentages of various types.

8.2 Hypothesis testing

The main evaluation criterion of this study was: Product efficiency at 6 months after implantation. The study design was a single-arm objective performance criteria, so the confidence interval method was used for hypothesis testing.

The 95% confidence interval (CI) of the difference between the two groups will be calculated for the treatment response rate six months after treatment. If the lower limit is greater than the target value of 82.5%, the study device will be considered to achieve the expected efficacy. Confidence interval estimation method adopts binomial distribution accurate method.

8.3 Study completion

Tables are used to describe enrollment and completion status, including Screening Number, Enrollment Number, Completion Number, Incompletion Number and reasons, analysis data set, dropout rate, protocol deviation, etc.

Tables on information on subjects who dropout/not entered the PPS, including screening number, date of informed consent, dropout reason, whether completed the study, entered the PPS, FAS& SS, etc.

Tables on subject protocol deviation information, including screening number, protocol deviation number, deviation description, other deviation description, reason for deviation, other deviation reason description, etc.

8.4 Demographic sociological characteristics and baseline analysis

For FAS set：

Tables are used to describe subject information**:**

- Demographic sociological characteristics, including age, gender, ethnicity, [redacted] etc;
- Past and current medical history, including history of ocular disease other than the study disease and a 2-year history of non-ocular disease (No/Yes), Past surgical history (No/Yes), whether the eye ever been treated surgically (No/Yes), current medical history--cataract conditions (Left Eye/ Right Eye, cataract type and score—posterior subcapsular, anterior subcapsular , cortical cataract, perinuclear cataract);
- Allergy history (No/Yes);

- Selected eye (Left Eye, Right Eye), reason, whether the selected eye is the primary eye;
- Pre-operative ophthalmic examination (described for the enrolled study eye only), including :
  - ✧ Best corrected visual acuity examination (not examined/examined without valid data/examined and valid data has been obtained, type of vision chart , optotypes used, distance in cm, study eye CDVA in logMAR);
  - ✧ Uncorrected visual acuity (not examined/examined without valid data/examined and valid data has been obtained, type of vision chart, optotypes used, distance in cm, study eye UDVA in logMAR);
  - [redacted]
  - ✧ Slit lamp microscope examination (not examined/examined and valid data has been obtained/examined without valid data, study eye —whether cornea is abnormal, corneal edema grading, whether the anterior/posterior segment is abnormal, aqueous flare grading, abnormal fundus, eyelids/eyelashes for abnormalities, conjunctiva abnormal, conjunctival congestion, conjunctival edema);
  - ✧ Endothelial cell count (Yes/No, examination method (automatic counting, semi-automatic counting, manual auxiliary counting), study eye — endothelial cell count in cells/mm^2 (Mean value of 3 or 5 counts);

- ✧ Intraocular pressure (Yes/No, examination method (Goldmann applanation tonometer, no-contact tonometer), study eye intraocular pressure in mmHg);
- ✧ OCT examination (not examined/examined and valid data has been obtained/examined without valid data, study eye —abnormal fundus);

[redacted]

- Non-study eye record: whether to implant 621P;

Descriptive statistical analysis was performed on the baseline data.

Tables on demographic and sociological characteristics of baseline subjects, including screening number, informed consent date, gender, date of birth, height(m), weight(kg), etc.

Tables on information on the subject's past medical history, including screening number, number, disease name, start time, whether is being treated , healed, whether it is an eye disease, etc.

Tables on subjects' current medical history and ocular symptom information, including screening number, eye with cataract, date of diagnosis, cataract type and score-posterior subcapsular, anterior subcapsular, cortical cataract, perinuclear cataract, etc.

Tables on subjects' eye surgery history information, including screening number, number, eyes, surgery name, surgery time, etc.

Tables on subjects' past surgical history information, including screening number, surgical history serial number, surgery name, surgery time, etc.

Tables on subjects' allergy history information, including screening number, history of allergies, if there are allergens, etc.

Tables on subject pre-operative ophthalmology examination —best corrected visual acuity examination and uncorrected visual acuity information, including screening number, examination item, whether examination, examination date, type of

vision chart, optotypes, distance cm, eye (Left Eye /Right Eye), CDVA/UDVA (LogMAR), etc.

[redacted]

Tables on subject pre-operative ophthalmology examination —objective refraction and subjective refraction information, including screening number, examination item, whether examination, examination date, eye(Left Eye/Right Eye), whether examination, spherical power, cylinder power, axis position A, spherical equivalent refraction, etc.

Tables on subject pre-operative ophthalmology examination —slit lamp microscope examination information, including screening number, whether examination, examination date, eye (Left Eye /Right Eye), whether examination, whether cornea is abnormal, corneal edema grading, whether the anterior/posterior segment is abnormal, aqueous flare grading, abnormal fundus, eyelids/eyelashes for abnormalities, conjunctiva abnormal, conjunctival congestion , conjunctival edema, etc.

Tables on subject pre-operative ophthalmology examination — endothelial cell count information, including screening number, whether examination, examination date, examination method, eye(Left Eye/Right Eye), whether examination, result 1, result 2, result 3, whether the error of 3 examination results exceeds 4%, result 4, result 5, etc.

Tables on subject pre-operative ophthalmology examination —Intraocular pressure information, including screening number, whether examination, examination date, examination method , eye (Left Eye /Right Eye), whether examination, result, etc.

Tables on subject pre-operative ophthalmology examination — OCT information, including screening number, whether examination, examination date, eye (Left Eye /Right Eye), examined and valid data has been obtained, abnormal fundus, etc.

Tables on subjects screening summary information, including screening number, whether enrolled, selected eyes , reason , whether the selected eye is the primary eye, etc.

[redacted]

8.5 Combined therapy and concomitant medication

For safety data set:

Tables are used to describe combined therapy rate, concomitant medication rate.

Tables on subject combined therapy situation, including screening number, non-drug treatment number, non-drug treatment name, start date, end date, treatment cause, indication#1, indication#2, indication#3, etc.

Tables on subject concomitant medication situation, including screening number, concomitant medication number, approved drug names, start date, route of administration, dose, unit, frequency, still in use, end date, treatment cause, indication#1, indication#2, indication#3, etc.

[redacted]

8.7 Effectiveness Analysis

8.7.1 Primary effectiveness endpoint

Tables are used to describe product effectiveness at 6 months after implantation

and its 95%CI was calculated. If the lower limit of 95% CI was greater than or equal to the target value (82.5%), the primary study index was achieved.

Applicable to FAS and PPS.

[redacted]

8.8 Safety analysis

(1) Post-operative slit lamp microscope examination—cornea, anterior and posterior segments, fundus, IOL

Tables are used to describe safety events from slit lamp microscope examination at different visit point (postoperative 1 day, 1 week ± 1 day, 1 month ± 7 days, 3 months ± 14 days and 6 months ± 30 days) , including **cornea complication** (corneal edema grading, corneal fold etc.), **anterior and posterior segment inflammations** (aqueous flare grading, buoyant cells of anterior chamber , hypopyon, endophthalmitis etc.), **fundus complications** (cystoid macular edema, retinal detachment, macular degeneration etc.), **IOL performance**(IOL decentration , tilt, rotation, dislocation, opacity, etc.).

Tables on information of slit lamp microscopy for each visit point of the subject, including screening number, visit point, whether examined, examination date, whether the cornea is abnormal, corneal edema grading, whether the anterior/posterior segment is abnormal, aqueous flare grading, abnormal fundus, whether the IOL is abnormal, description of IOL abnormality, whether the incision is abnormal, description of incision abnormality, IOL aqueous flare evaluation, whether there are other abnormalities, and description of other abnormalities, etc.

(2) OCT examination —fundus complications

Tables are used to describe **fundus complications** (cystoid macular edema, retinal detachment, macular degeneration, etc.) at 1 month ± 7 days and 6 months ± 30 days postoperatively on OCT.

Tables on subject OCT examination information at postoperative 1 month ± 7 days , including screening number, visit point, examined and valid data has been obtained , examination date, fundus conditions, etc.

(3) Endothelial cell count

Tables are used to describe the corneal endothelial cell counts at 3 months ± 14 days and 6 months ± 30 days after surgery.

Tables on subject corneal endothelial cell counts examination information, including screening number, visit point, whether examination, examination date, examination method, result 1, result 2, result 3, whether the error exceeds 4%, result 4, and result 5, etc.

(4) Intraocular pressure examination—Intraocular pressure

Tables are used to describe the subject's intraocular pressure at 1 day, 1 week ± 1 day, 1 month ± 7 days, 3 months ± 14 days, and 6 months ± 30 days after surgery, including the results of intraocular pressure examination (mmHg), and clinical assessment, etc.

Tables on subjects' intraocular pressure examination results, including screening number, visit point, whether examination, examination date, examination method, result, clinical assessment, etc.

(5) PCO assessment and Nd:YAG laser posterior capsulotomy

Tables are used to describe PCO situation and Nd:YAG laser posterior capsulotomy in subjects at 1 month ± 7 days, 3 months ± 14 days, and 6 months ± 30 days postoperatively, including the presence or absence of PCO, PCO grading, and whether Nd:YAG laser posterior capsulotomy was performed.

Tables on information on PCO assessment and Nd:YAG laser posterior capsulotomy in subjects (1 month ± 7 days, 3 months ± 14 days, and 6 months ± 30 days postoperatively), including screening number, visit point, presence of PCO, PCO grading, whether Nd:YAG laser posterior capsulotomy was performed, treatment date, and treatment outcome, etc.

(6) Secondary surgery

Tables are used to describe the occurrence of secondary surgery in the subjects, which can be divided into two situations: (1) If the secondary surgery occurred only once, the statistics were the number and percentage of cases; ② If the secondary surgery occurs but is not limited to one, the number and percentage of cases (that is, according to the number of cases, no matter how many times it occurs, it is regarded as occurring), the number of cases and percentage (total number/total number of cases) are given respectively.

Tables on subject's secondary surgery information, including screening number, visit point, whether new IOL secondary surgery occurred, surgery reason, treatment result, etc.

(7) Adverse events

Tables are used to describe the incidence of adverse events and serious adverse events during the study period.

Tables on subject adverse event information, including screening number, AE serial number, AE name, specific description of AE, time of notification, occurrence time, end time, degree, outcome, relationship with surgery, relationship with study device, if relevant, whether the adverse event is expected, measures taken on study device, error correction treatment, if available, whether serious adverse event, SAE classification, whether to report to regulatory authorities , report date, whether the trial was withdrawn due to AE, etc.

Tables on serious adverse events in subjects, including screening number, SAE serial number, SAE name, date of use, date of occurrence, date of notification to investigator, date of notification to sponsor, SAE classification, date of death, measures taken for study device, regression, relationship to study device, whether device deficiency, whether expected, whether other serious safety risk information, whether widespread SAE or other significant safety issue, details of occurrence and treatment, and what risk control measures were taken.

(8) Device deficiency

Tables are used to describe subject device deficiency occurrence situation, including whether it occurs, occurrence type, etc. etc.

Tables on subject device deficiency information, including screening number, device deficiency number, device serial No., lot No., device deficiency name, occurrence date, the site is informed of the date the deficiency occurred, the measures taken, any medical events/illnesses or injuries that resulted, the initial cause analysis of the event, the measures taken for the study device, etc.

9 Data Derivation

This section describes rules for the derivation of variables not directly recorded in the eCRF. Derived variables will be marked in subject data listings by “#” in the listing header.

Change from Baseline

Change from baseline will be calculated as follows:

Change from baseline = (post-baseline value) – (baseline value)

Visual Acuity Parameter [redacted]

[redacted]

Change from baseline VA

The difference in LogMAR (Δ) between the baseline VA and the postbaseline VA will be calculated and categorized as following:

- Δ ≤ -0.10 LogMAR ("1 or more better")
- -0.10 LogMAR < Δ < 0.10 LogMAR ("Same")
- 0.10 LogMAR ≤ Δ < 0.20 LogMAR ("1 worse")
- 0.20 LogMAR ≤ Δ < 0.30 LogMAR ("2 worse")

- 0.30 LogMAR ≤ Δ ("3 or more worse")

[redacted]

Test Distance Adjustments

No test distance adjustments will be done.

Time from Implantation and Durations

Time from implantation will be determined by comparing the respective date to the date of the implantation of the IOL:

Time from implantation = Date (e.g., date of visit) - Date of implantation

Duration from implantation = Time (time of measurement) – Time of surgery end +1

Time to Onset and Duration of Adverse Events

Time to onset and duration of adverse events will be calculated as follows:

- Time to onset = start date of AE - date of implantation
- Duration of adverse event = stop date – onset/worsening date + 1

Subjective/Objective Refraction

[redacted]

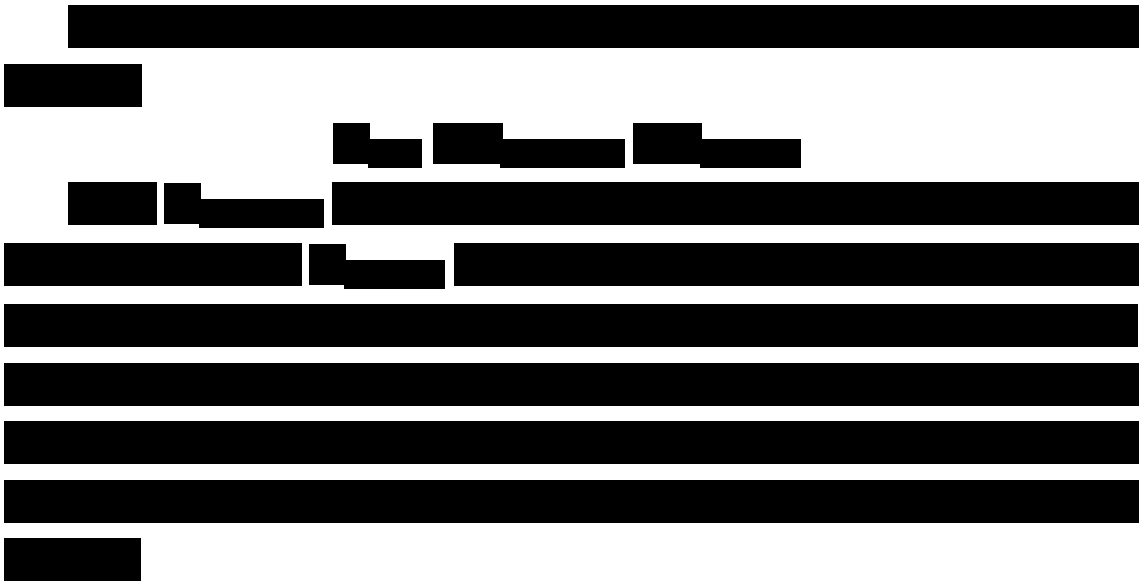
Spherical equivalent

SE will be derived from their cylinder component (using the minus cylinder notation) and sphere (tested at 400cm) [redacted]

If another test distance than 400cm is used the sphere at 400cm will be derived by conversion from the optical infinity adjusted sphere (see below).

[redacted]

[redacted]



Keratometry

For the analysis of keratometry the following conversion of keratometry values given in mm will be used:

$$\mathbf{K} = \frac{(n' - n)x1000}{R}$$

- n´= refractive index biometry
- n = refractive index air (1.0003)
- R = corneal radius in mm
- K = corneal power in dioptre

Endothelial Cell Count

The endothelial cell count (ECC) will be assessed through three measurements. For analysis, the mean of all counts or the single value (if only one measurement is available) will be used.

10 Statistical Results Output (table, chart, attached table, chart, list)

General Agreement

(1) The Programming Note in the document is a description of the programming or notes, not part of the table content, and is shown in *blue, italicized, 12-point font*. The part enclosed by "[ ]" is the specific classification of the count data, e.g. lymph node [unchecked/normal/abnormal], which means that the lymph nodes need to be displayed according to the 3 classifications of "unchecked", "normal" and "abnormal".

(2) Fractional Digits

Data type	**Display Fractional Digits**
P value	If the P-value >= 0.001, the 3-bit fractional digits are retained, otherwise it is displayed as "<0.001"
Counting	0
Percentage, Rate	1, if the percentage is 100%, it is "n (100)" or "n (100%)". If the percentage is zero, you do not need to display the percentage "0".
Mean, median, P25, P75, standard deviation, standard error, confidence interval	One digit more than the original data, the maximum fractional digits is 3 digits
Min, Max	Consistent with the original data digits, the maximum fractional digits is 3 digits
Derived data	General requirements. 1. Based on the number of bits of the original data before derivation, output the table according to the above statistic fractional digits. 2. The fractional digits are not retained for the derived values, but all data after the derivation is maintained. fractional digits can only be retained when calculating statistics in TFL. 3. The maximum fractional digits is 3 bits.

(3) Date and time

a. Separate the date and time with a "/";

b. Use "-" for missing date/time elements;

c. Study days are counted only when both dates are complete.

For example, if the first dose was administered on 2012-12-01, the following scenarios would occur:

Original record date	Original record time	Precision	Display format for date/time (study days)
2012-12-15	8:15	full date/time	2012-12-15/08:15 (15)
2012-12-15	8	minute loss	2012-12-15/08: -- (15)
2012-12-15	?:15	hour loss	2012-12-15/--:15 (15)
2012-12-15		total absence of time	2012-12-15 (15)
2012-12		day and time loss	2012-12---
2012		month, day and time loss	2012------
2012?15		month and time loss, but year and day are collected	2012----15
12-15		year loss,but month and day are collected	-----12-15
	8:15	all dates loss, but the time is collected	----------/08:15
	?:15	only collected minutes	----------/--:15
		date and time loss	

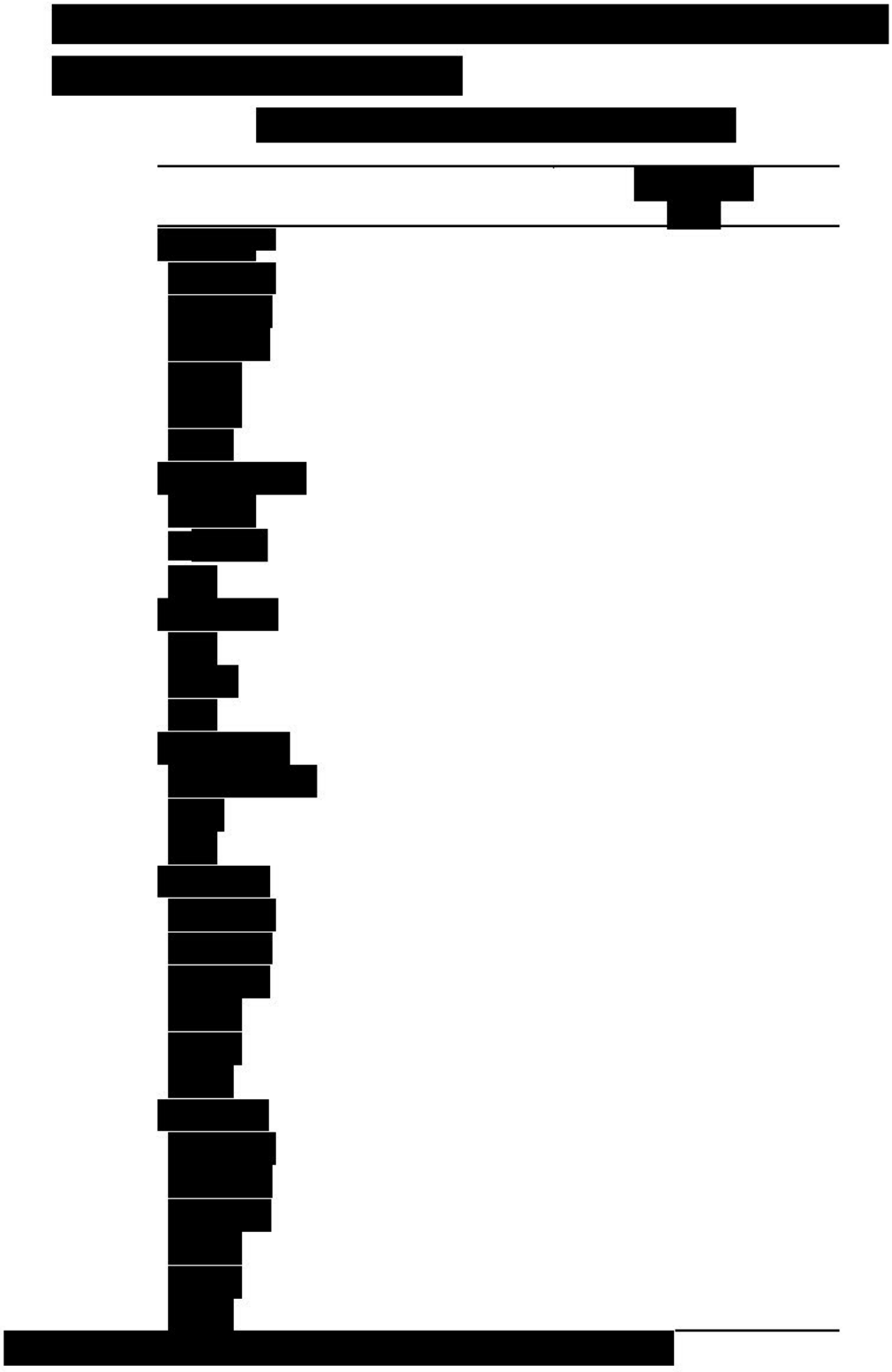
(4) General Descriptive Statistics

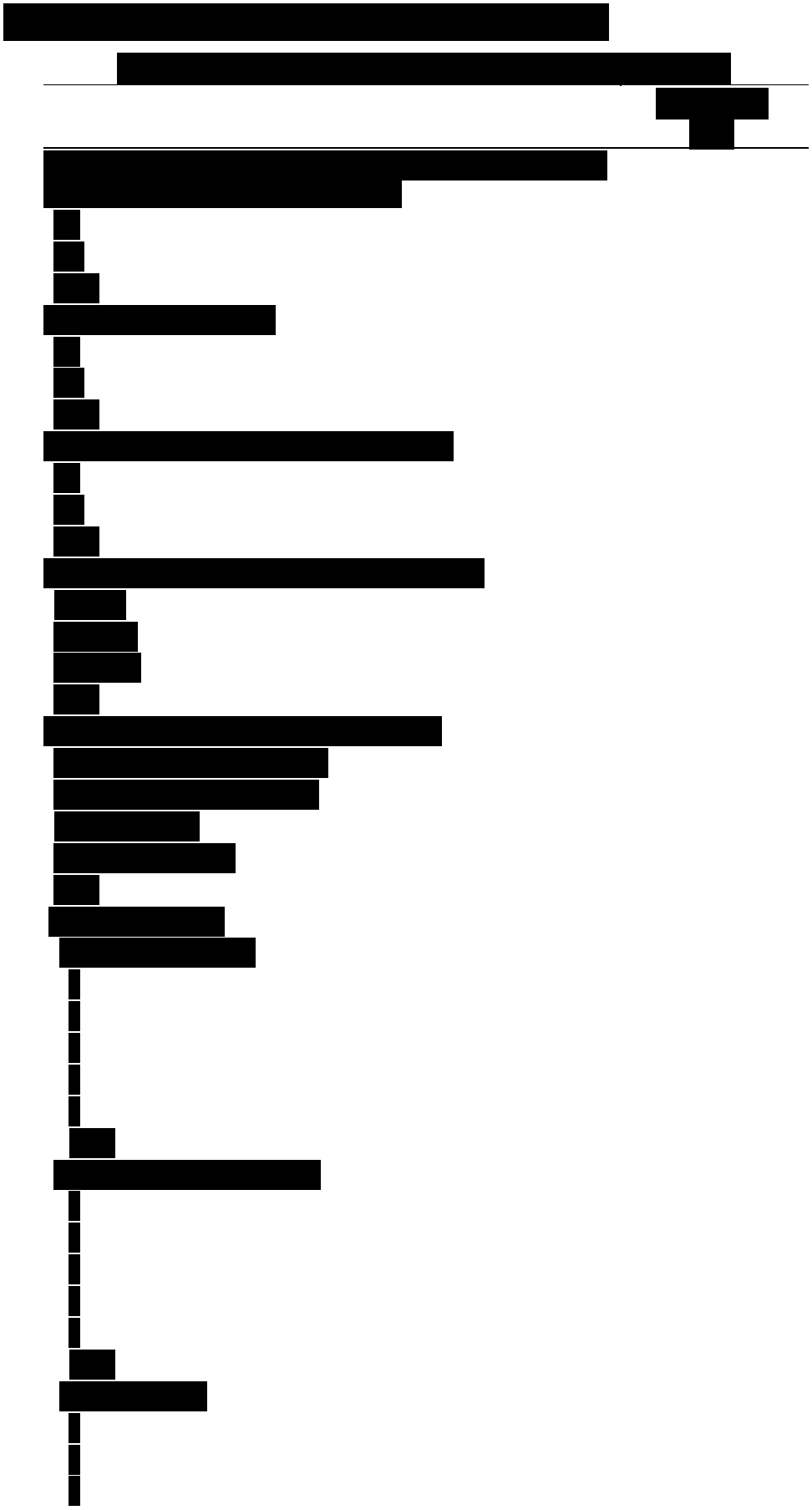
If not specified, the number of cases and percentage of each category will be calculated based on the order of the categories in the CRF, and the Total item will be added. For example, if the classification order of Gender in CRF is "Male" and then "Female", then the classification of Gender is "Male", "Female", "Total".

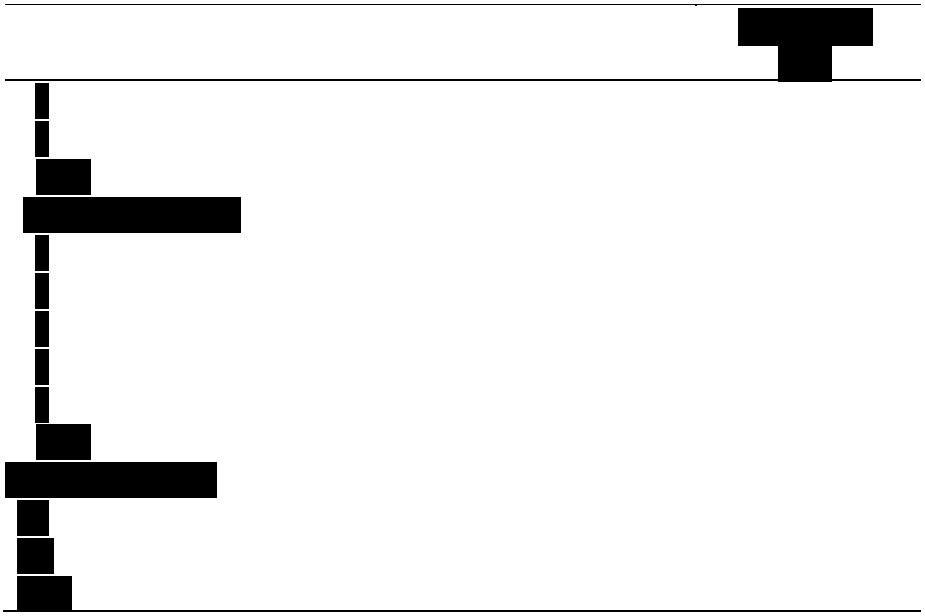
If not otherwise specified, for the measures, the following statistics are given in groups: number of cases, mean (standard deviation), median (Q1, Q3), (minimum, maximum), 95% confidence interval (lower, upper).



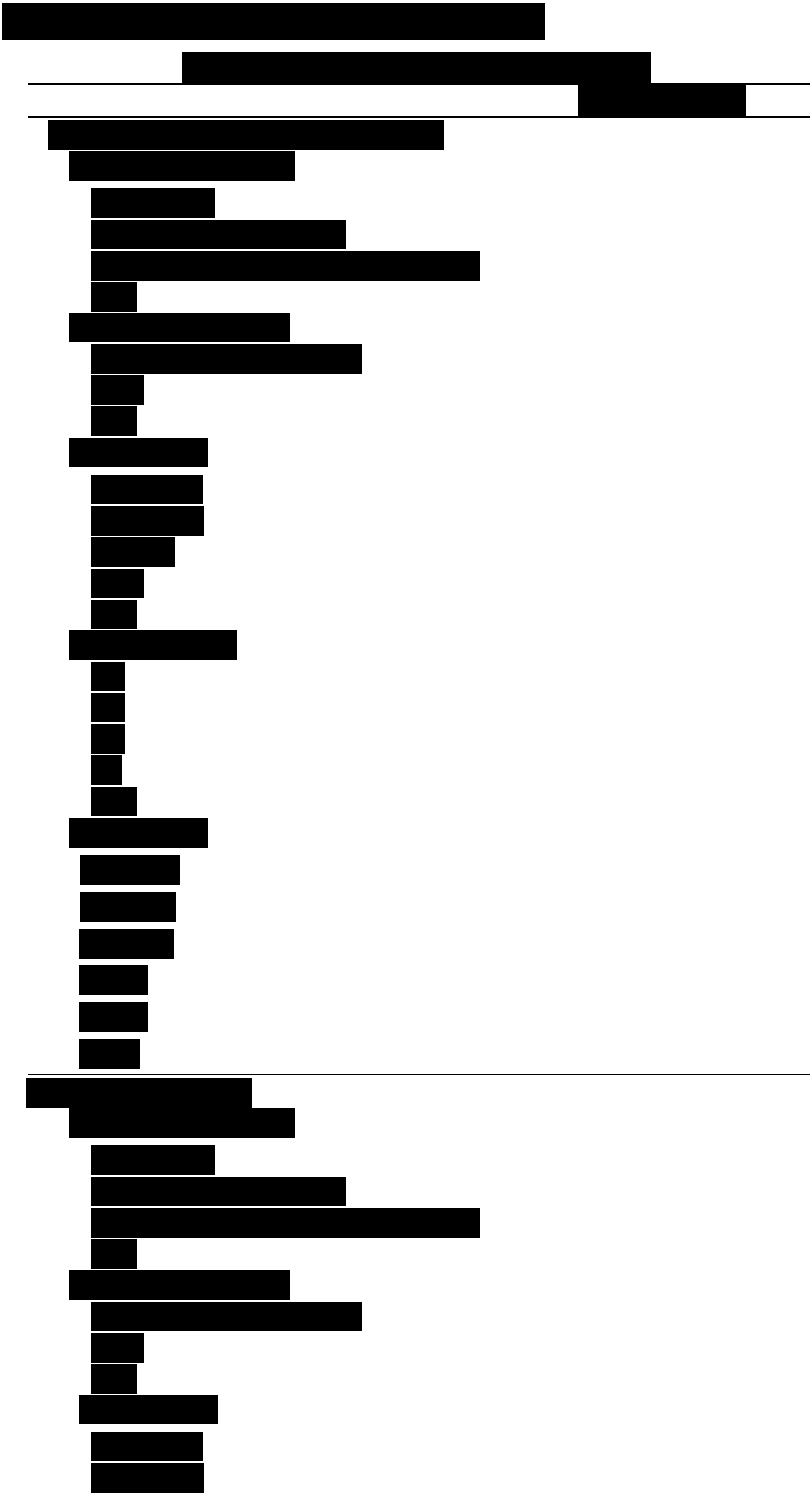


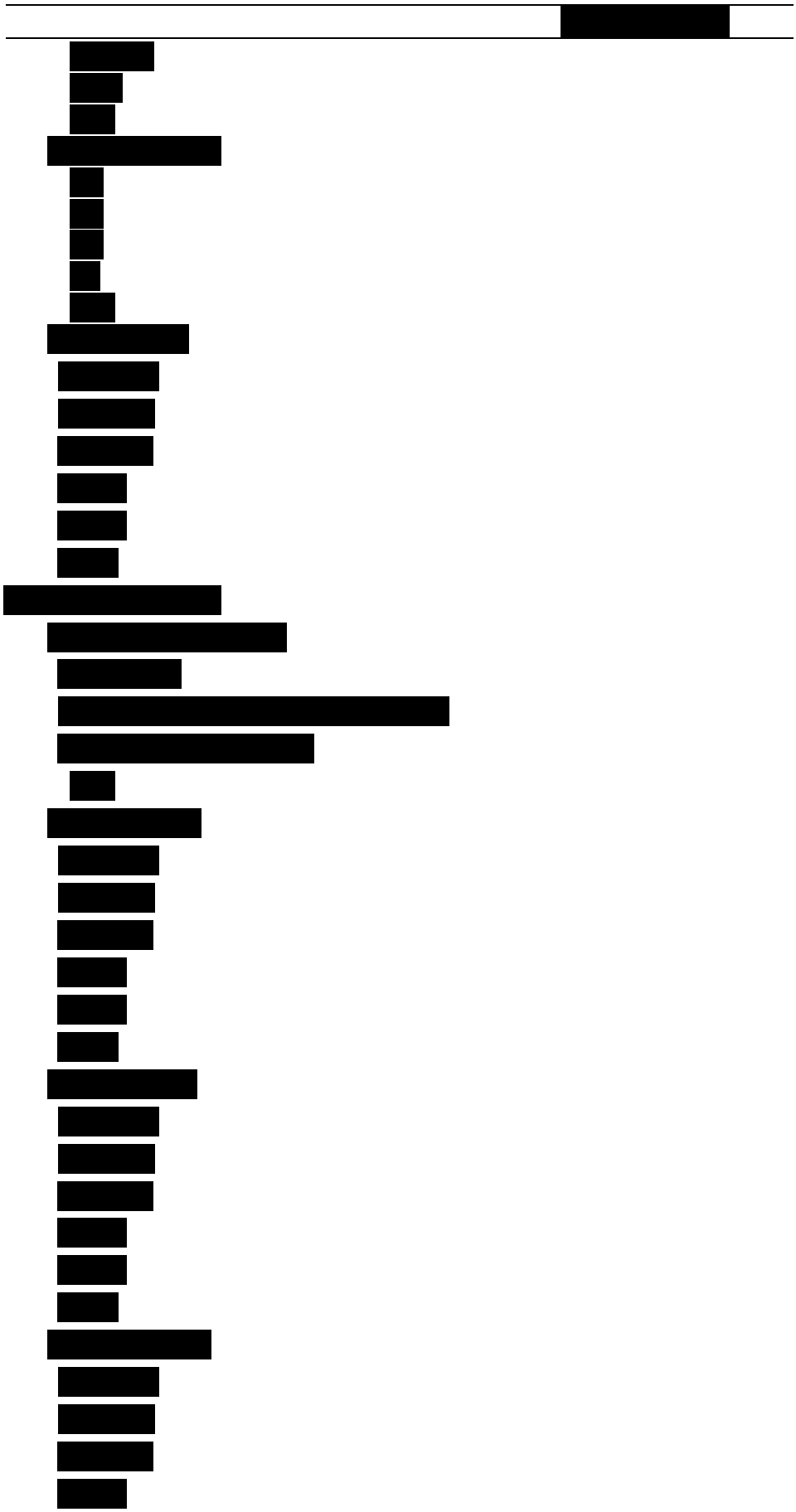














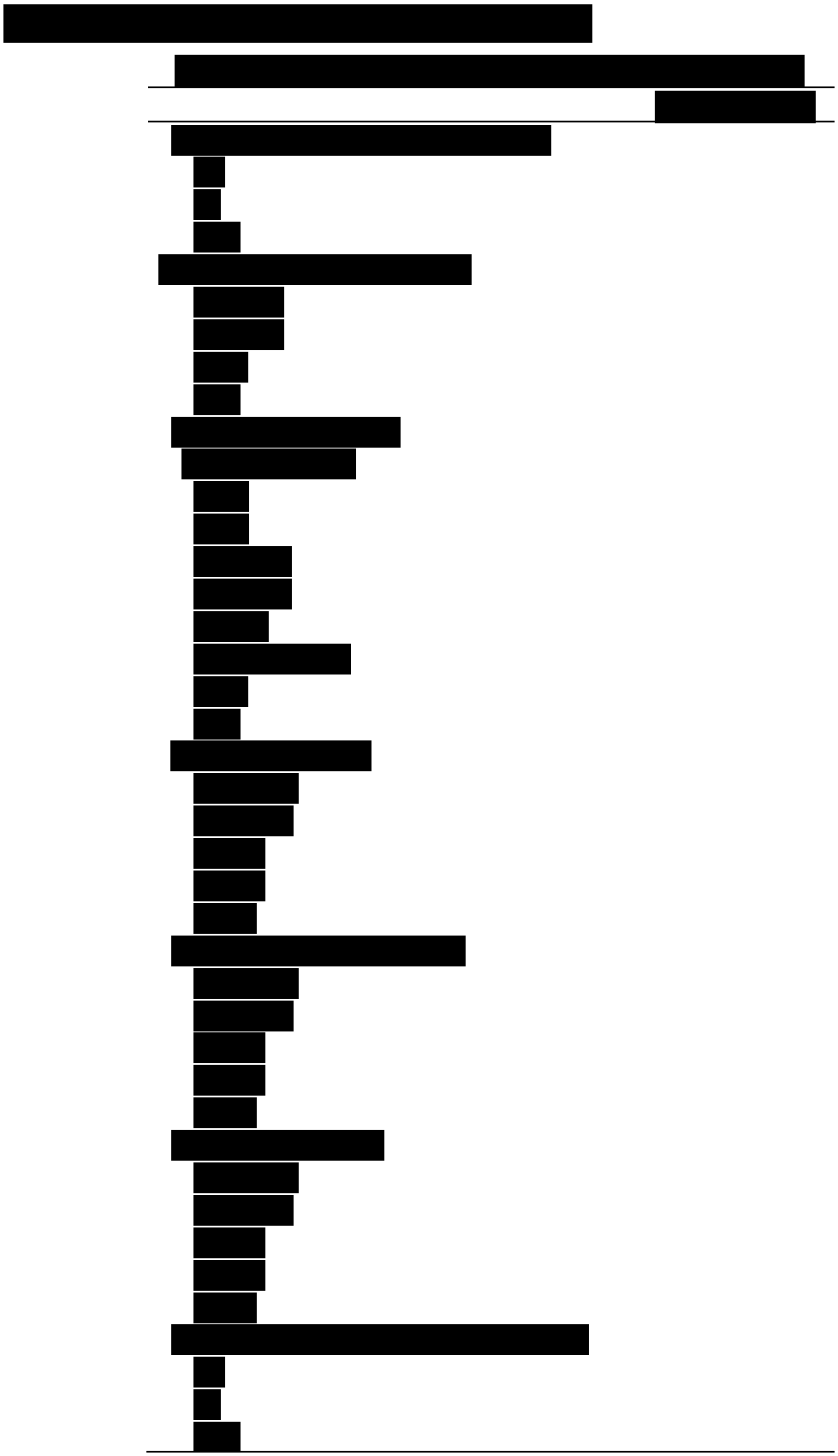












10.3 Effectiveness Evaluation

10.3.1 Primary effectiveness endpoint —Product efficiency at 6 months after implantation

Table 10.3.1.1 Comparison of product efficiency at 6 months after implantation(FAS)

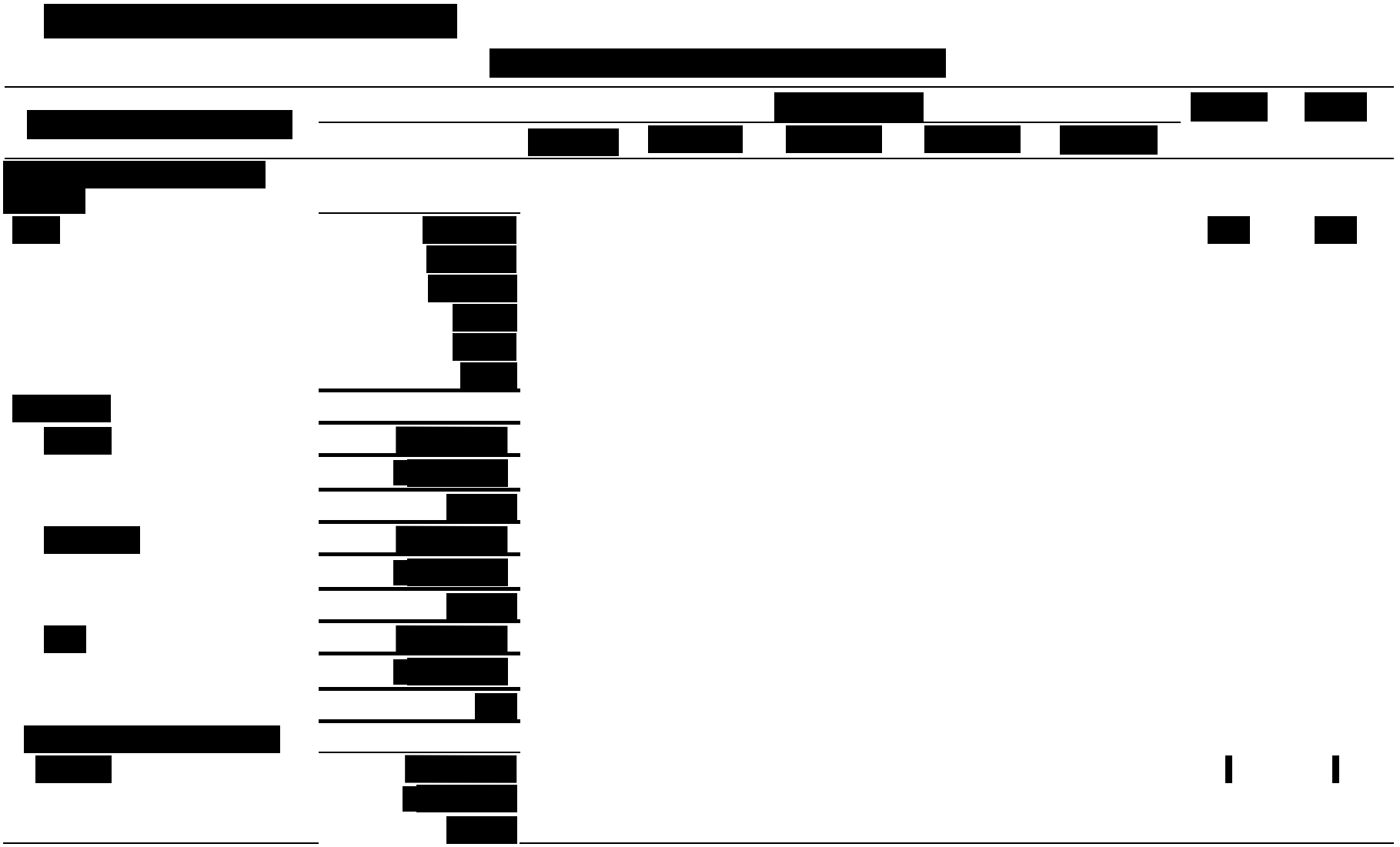
	Study group(N=)
Product efficiency at 6 months after implantation n(%)	
valid	
invalid	
Total	
effective 95% CI	

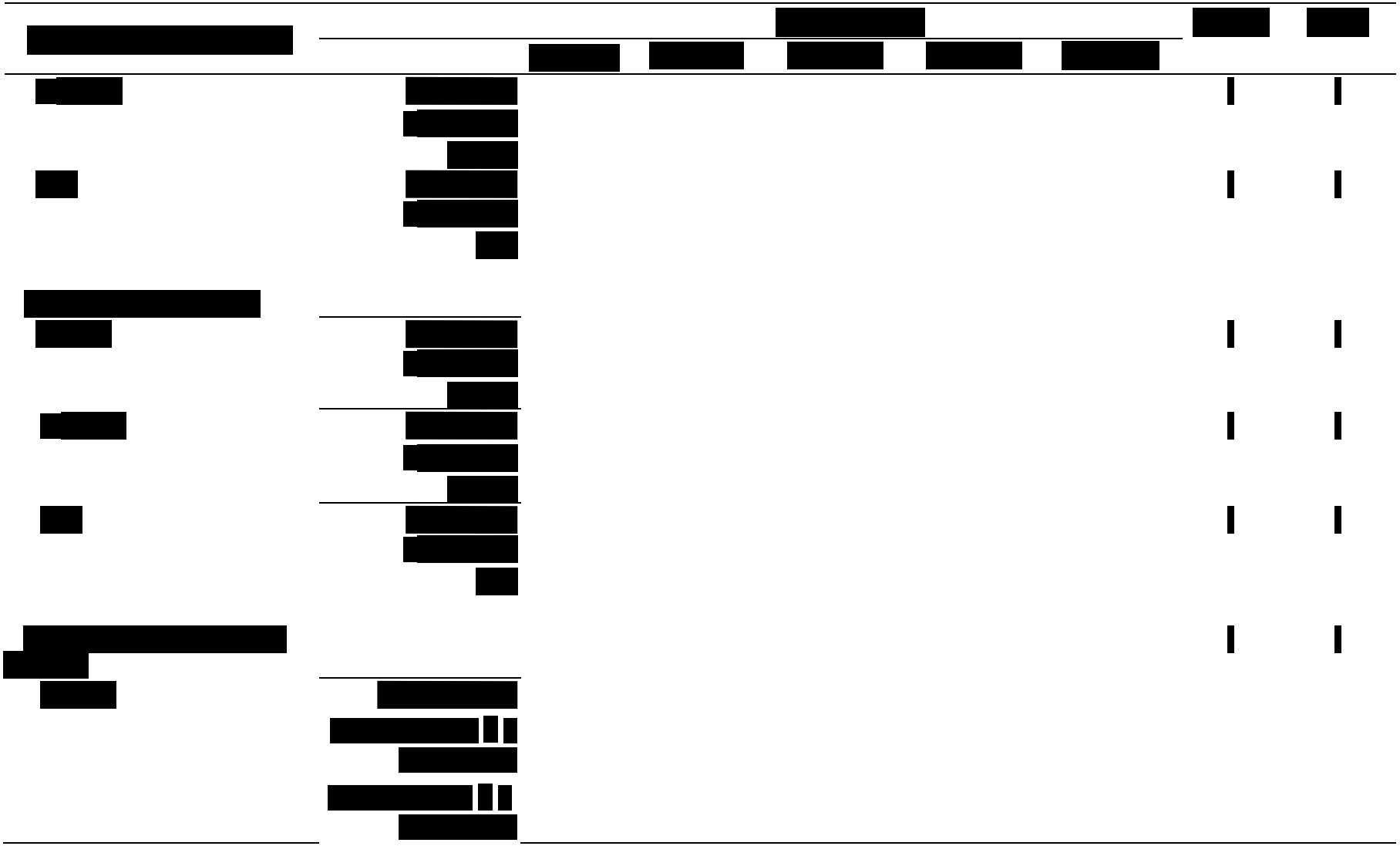
[Programming Note] Note the method of calculating 95% CI .

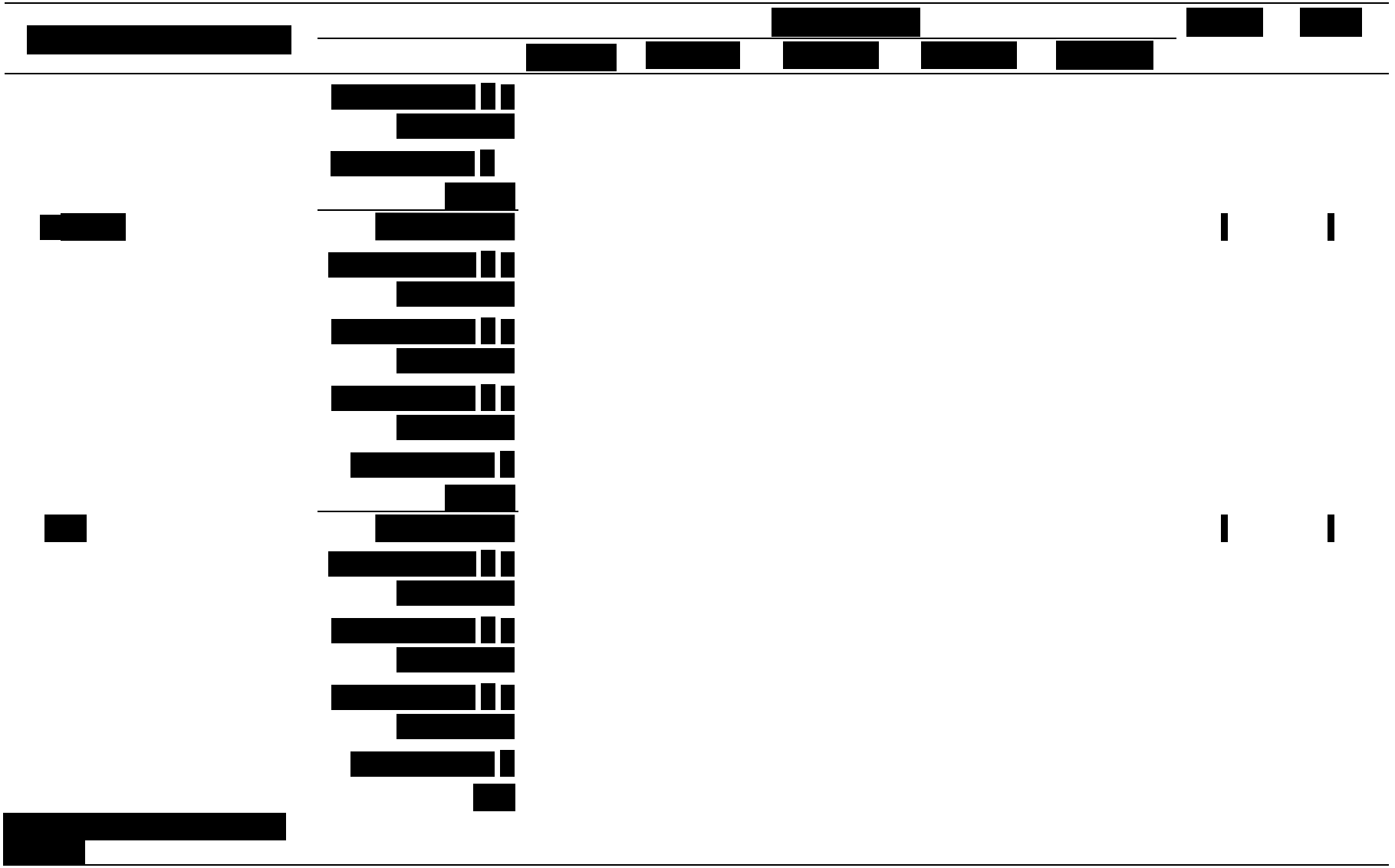
Table 10.3.1.2 Comparison of product effectiveness rate at 6 months after implantation (PPS)

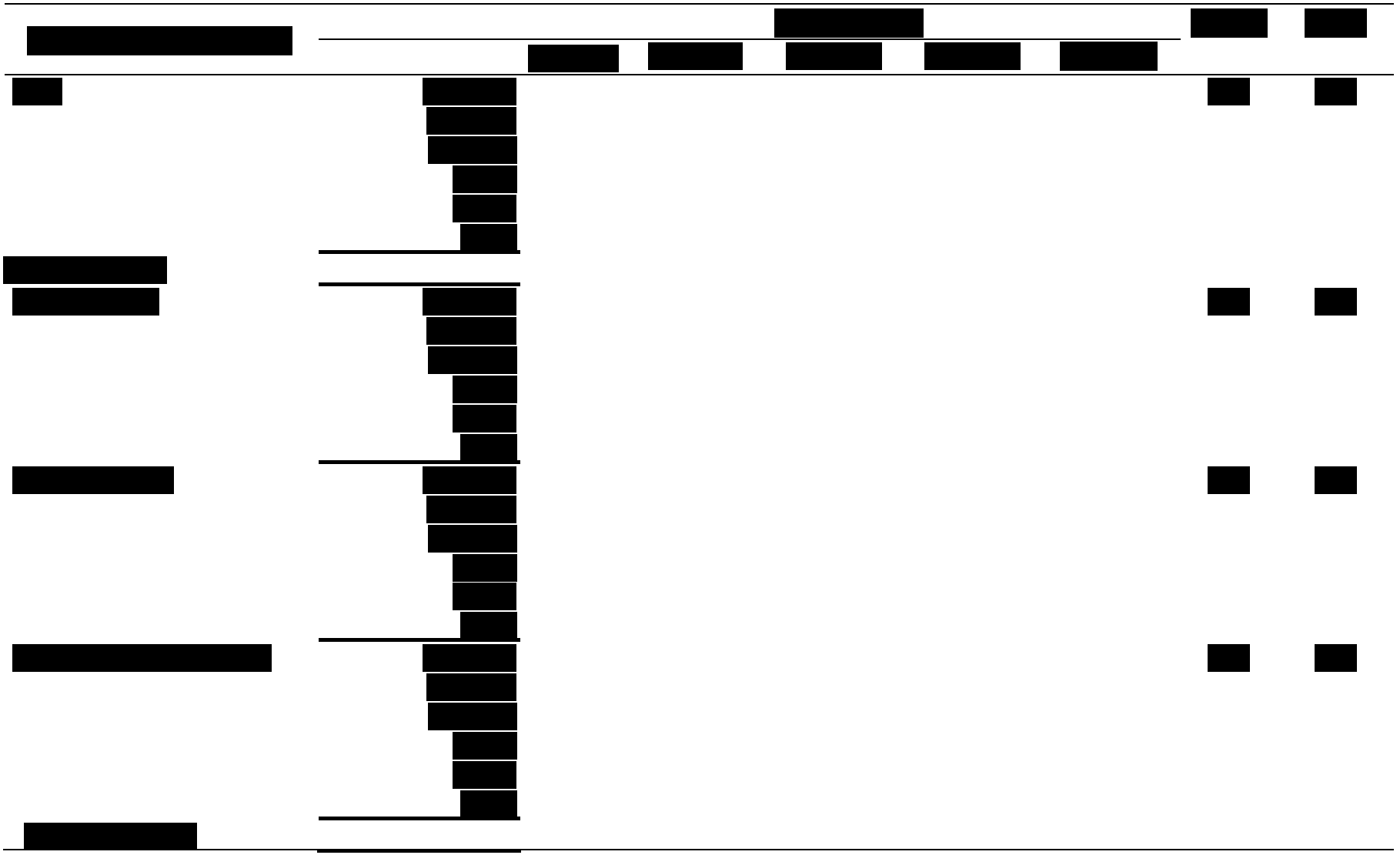
	Study group(N=)
Product efficiency at 6 months after implantation n(%)	
valid	
invalid	
Total	
effective 95% CI	

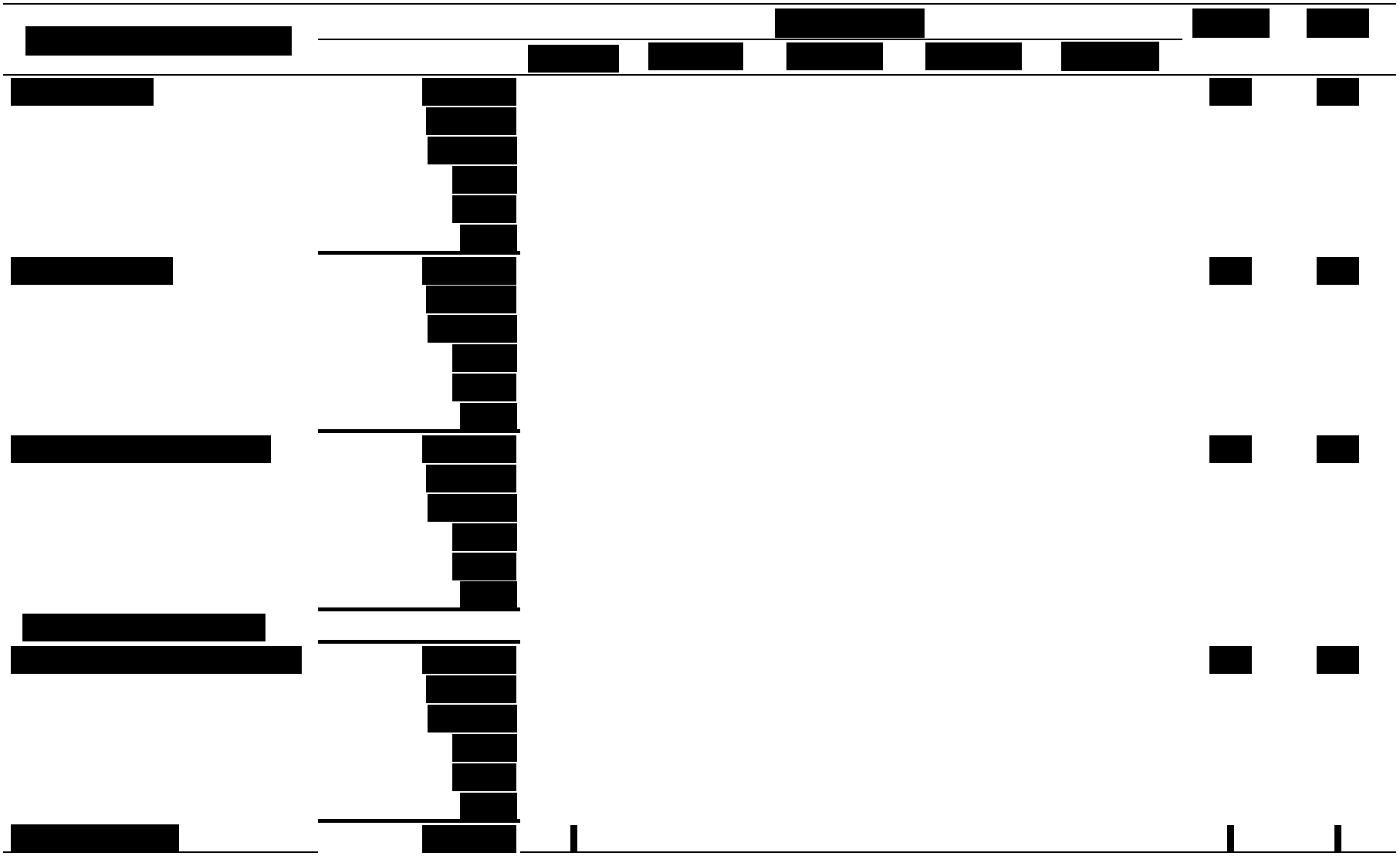
[Programming Note] Note the method of calculating 95% CI .

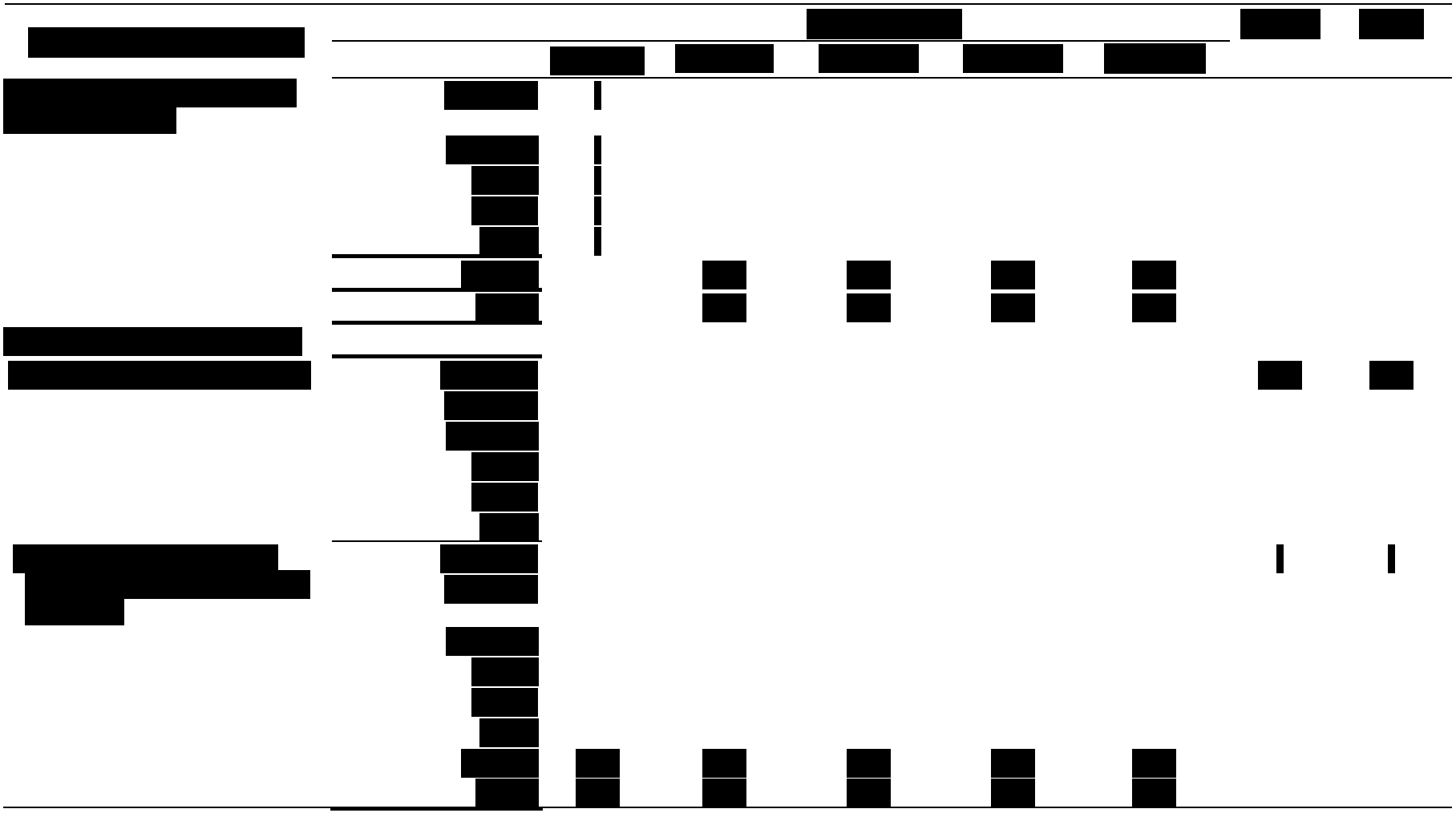




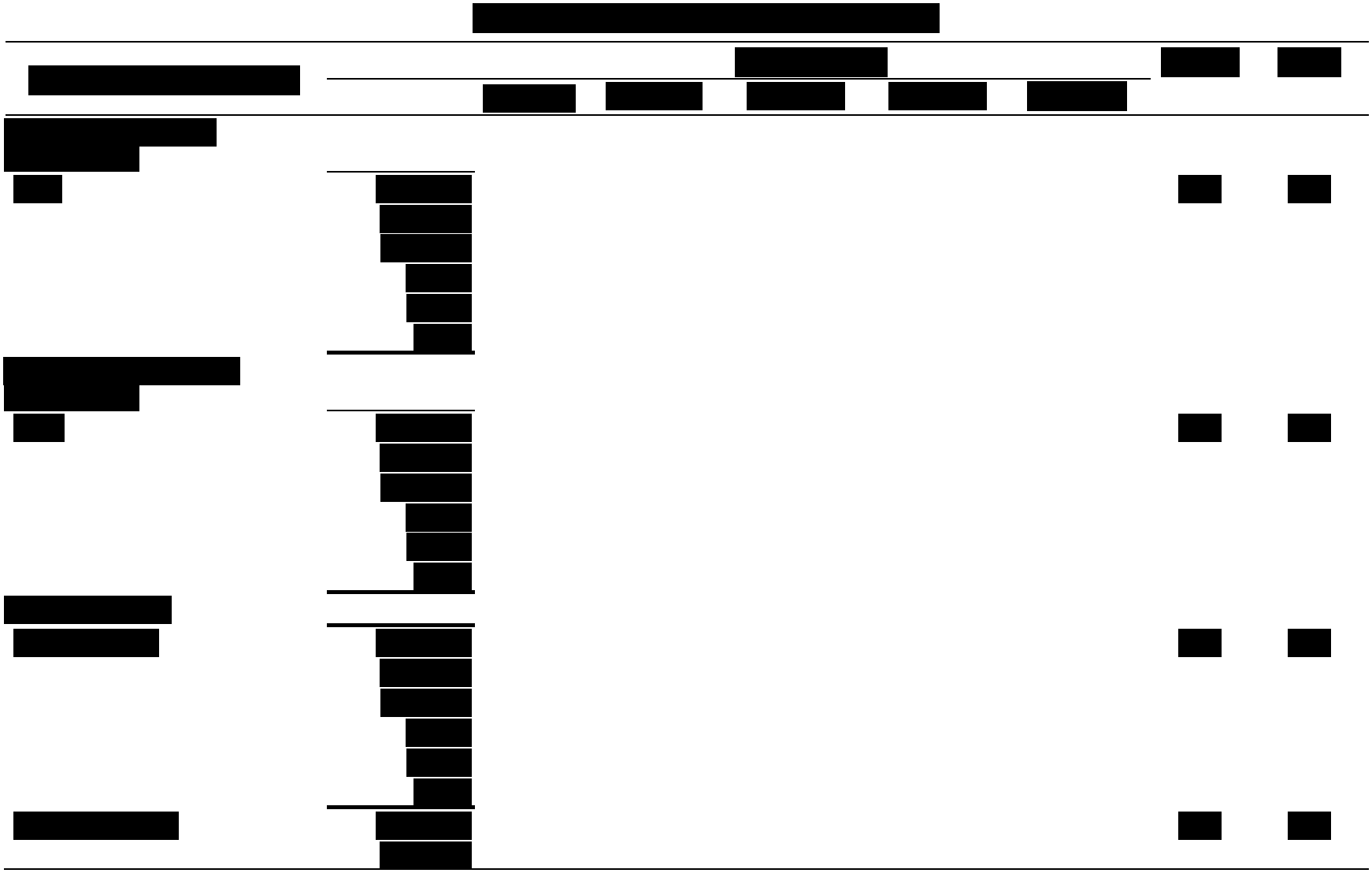


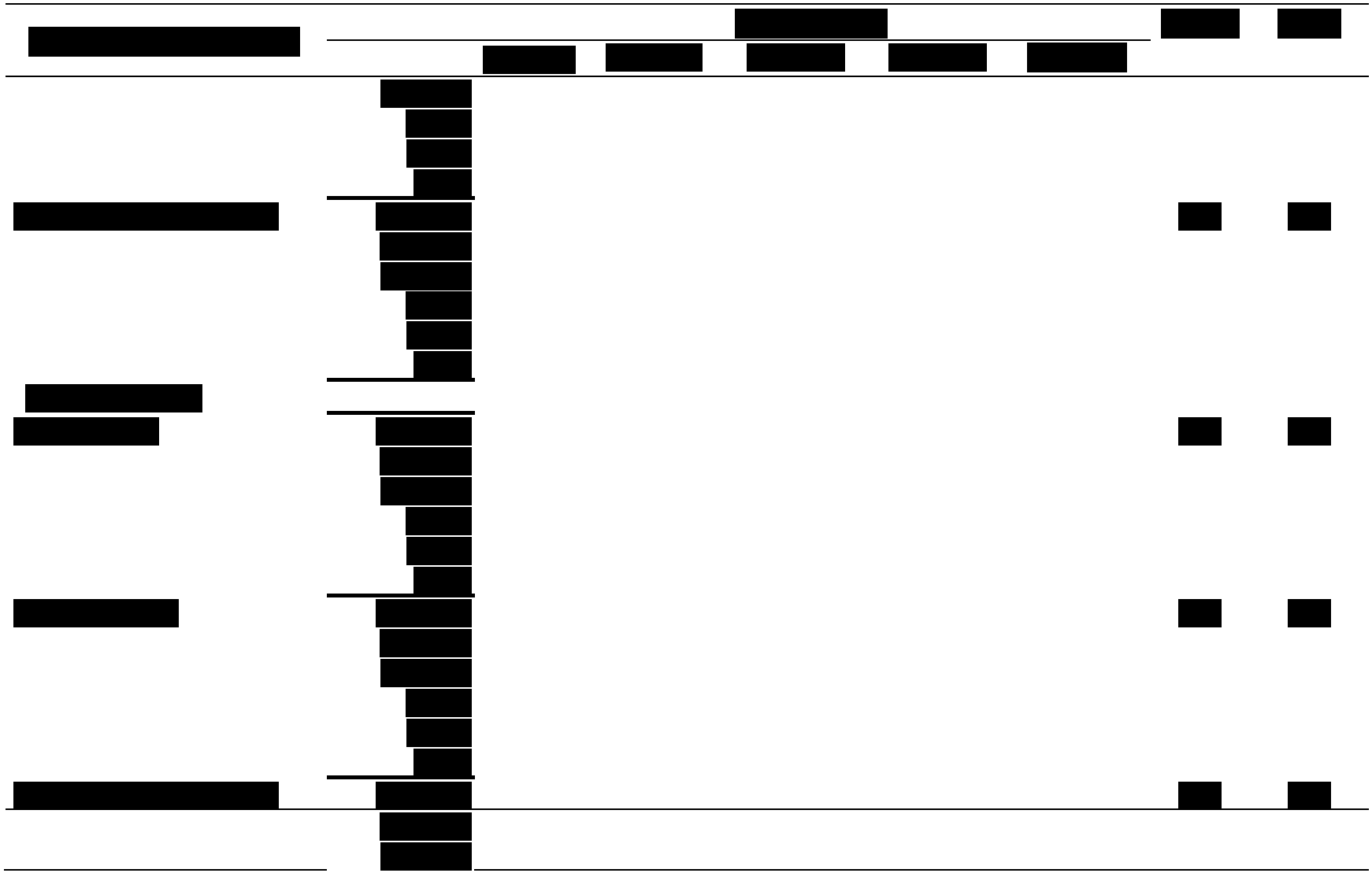


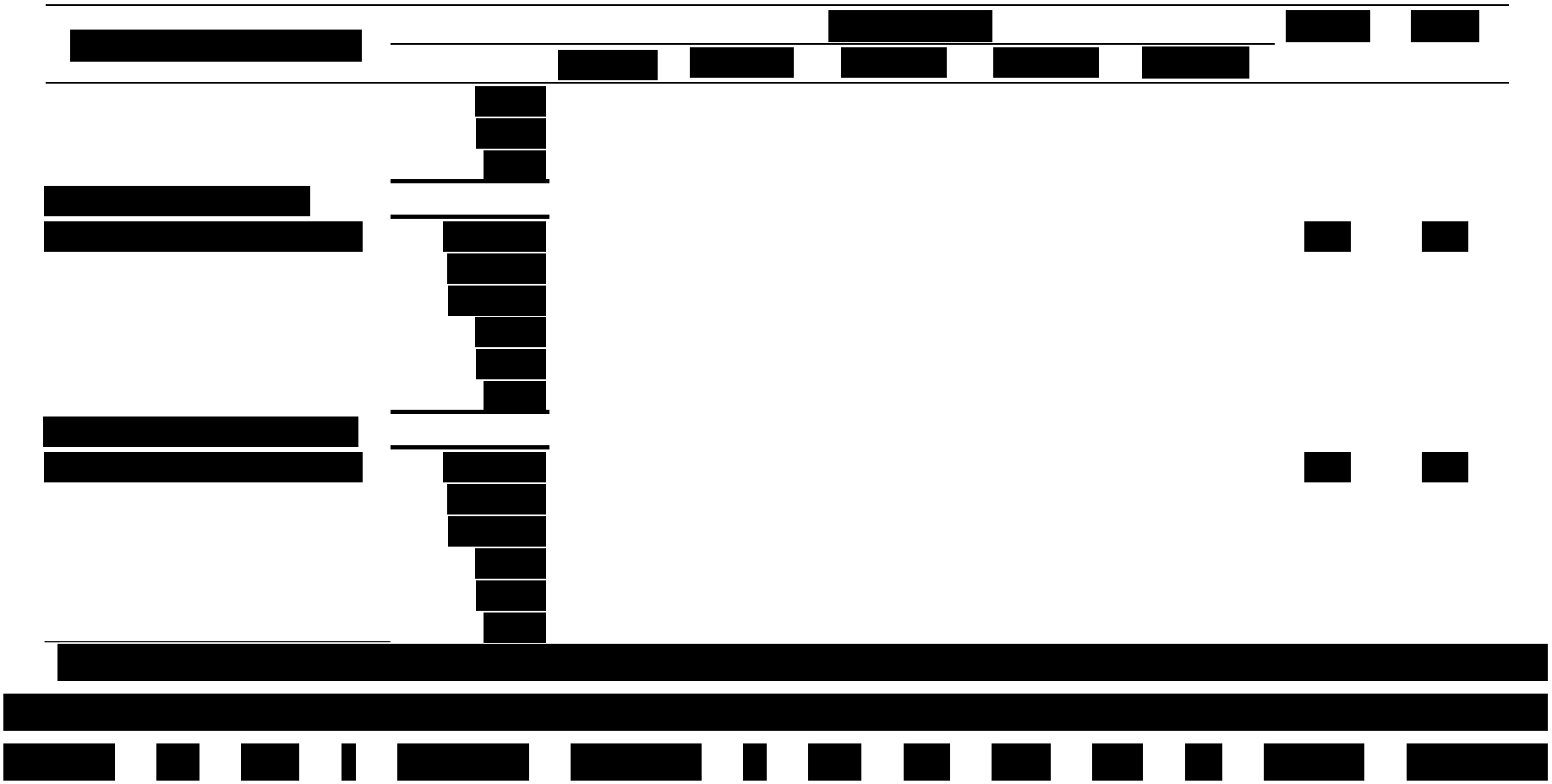




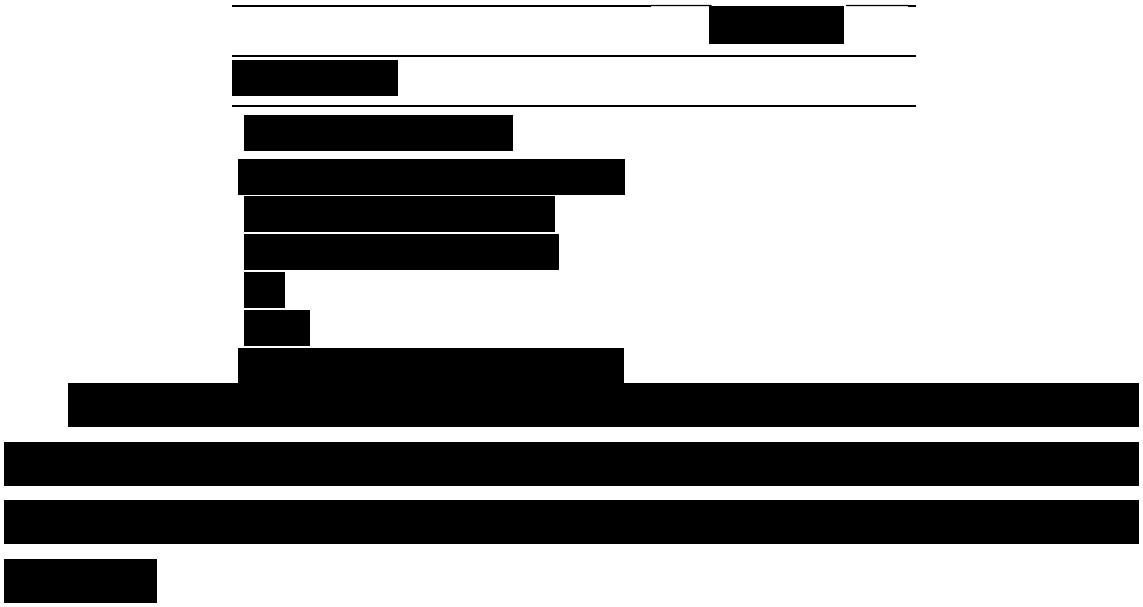




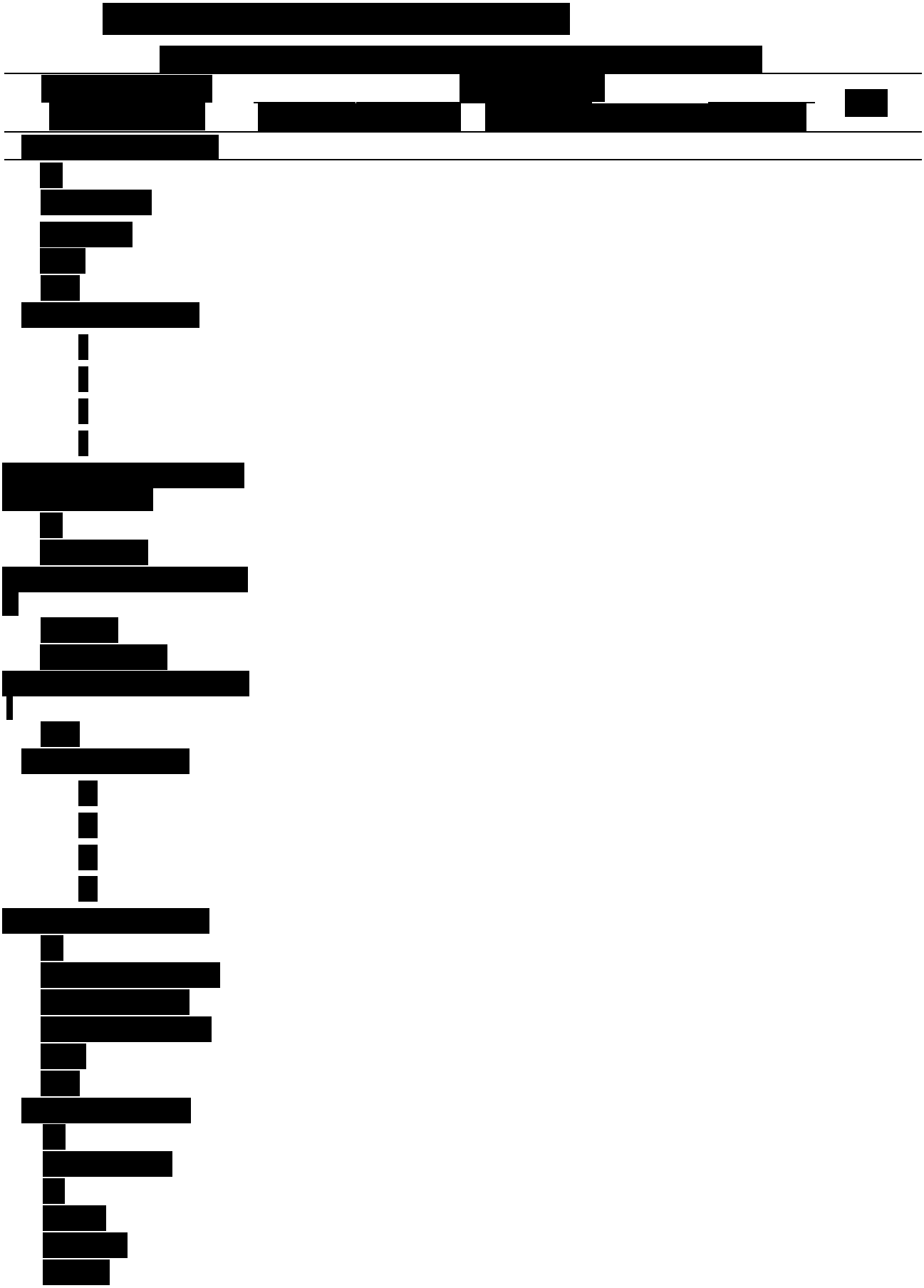


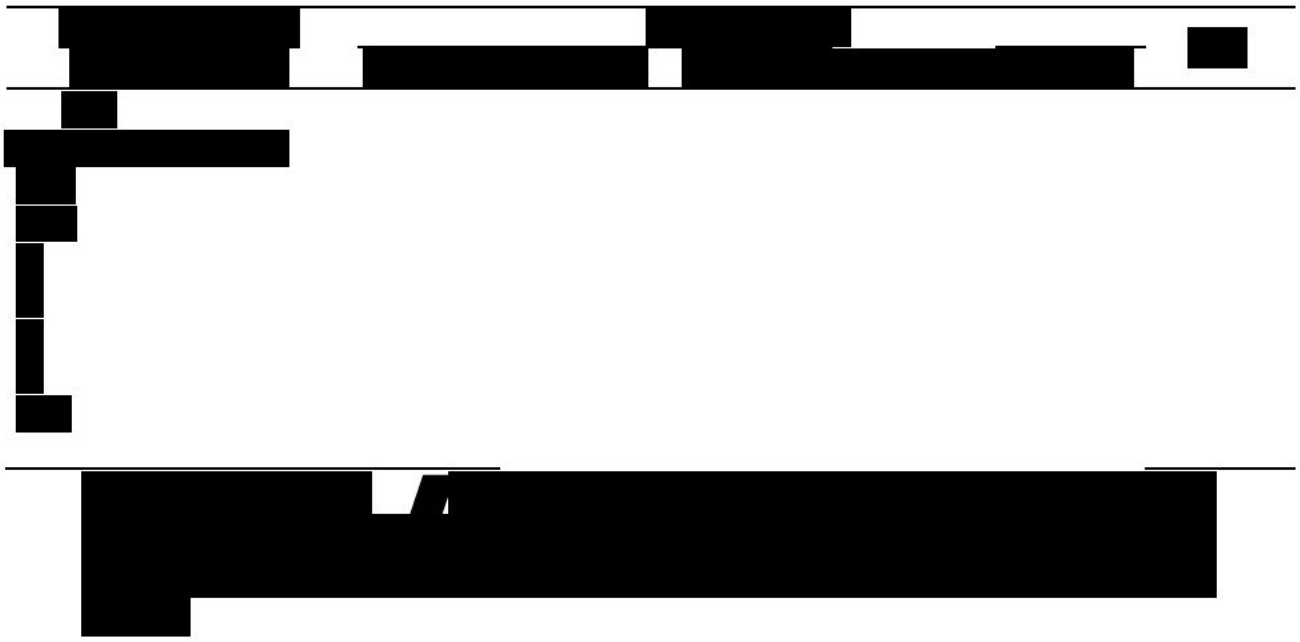








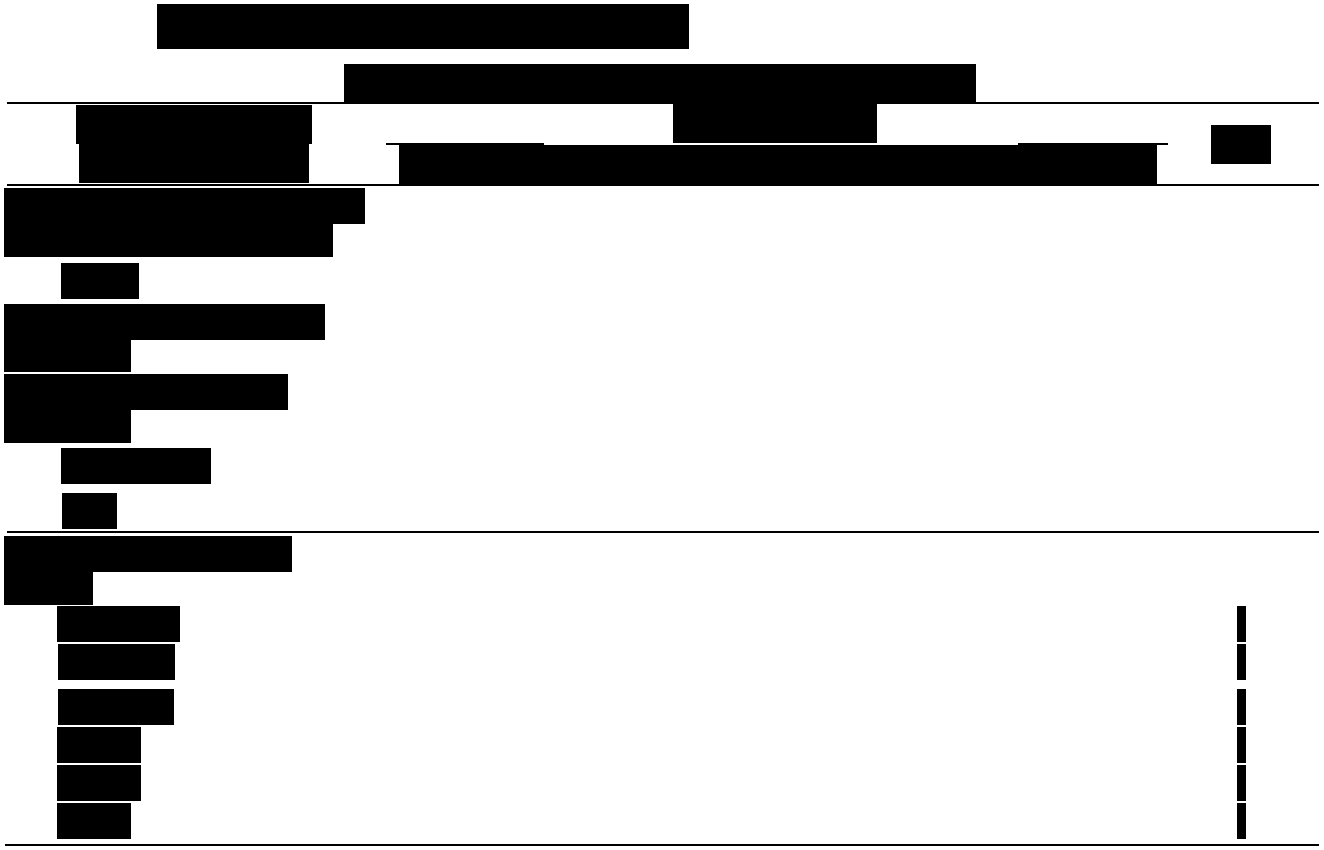


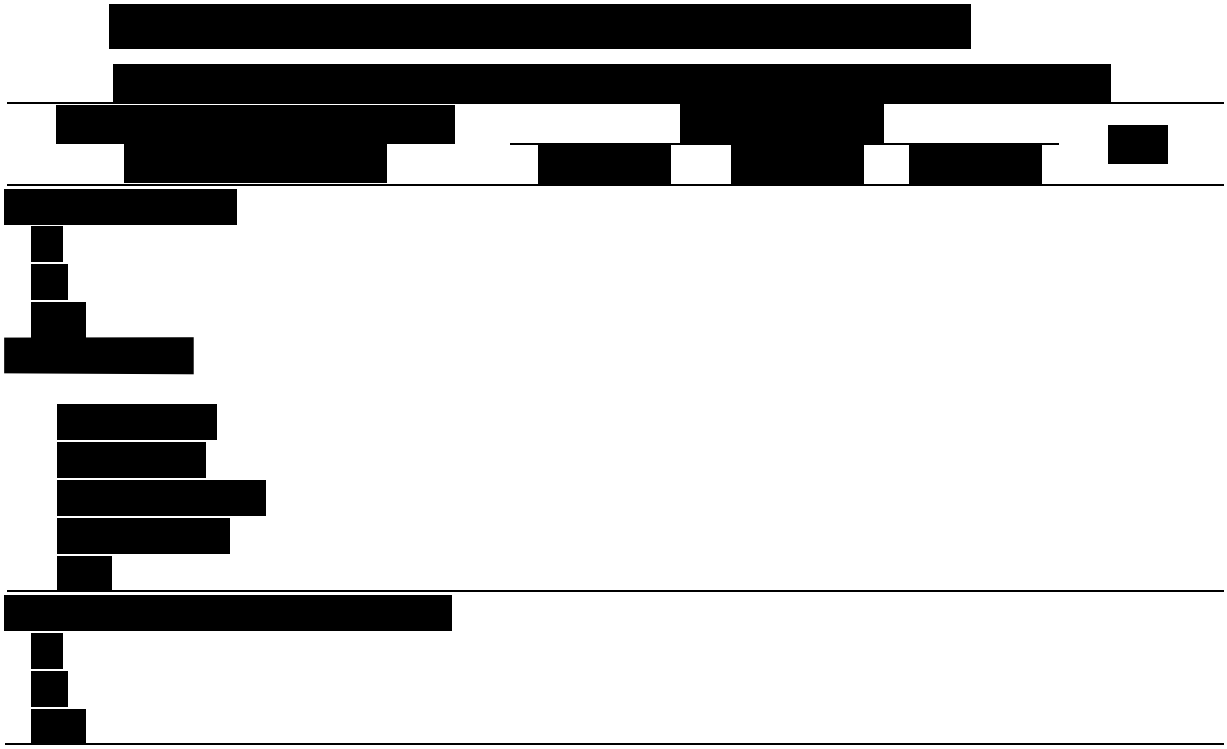


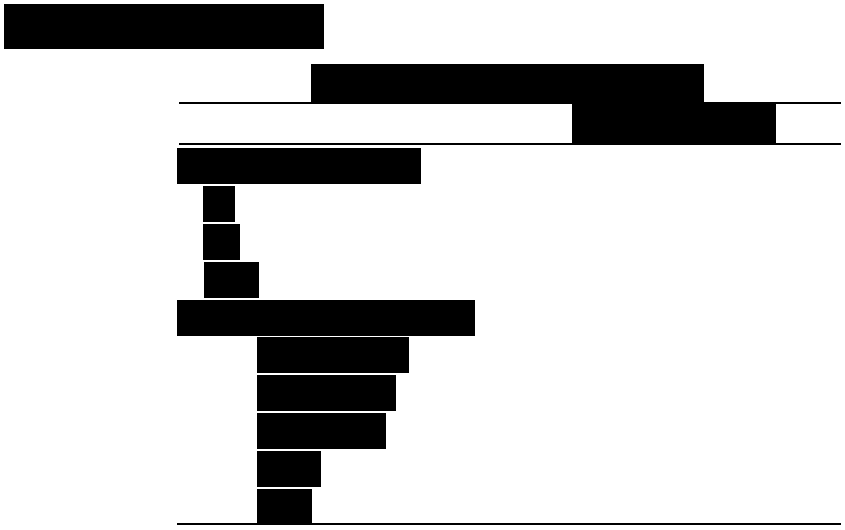


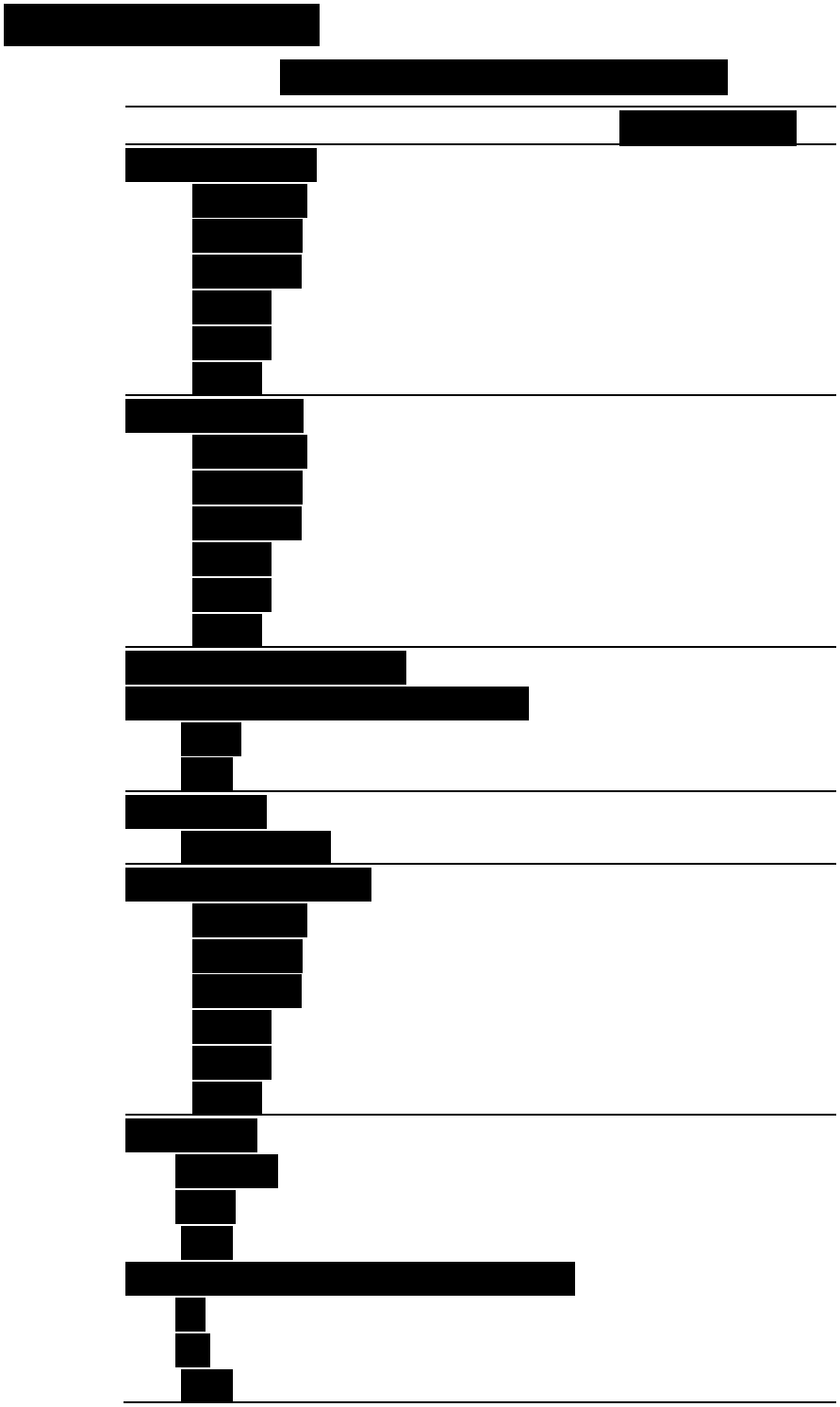


[Programming Note] @: The mean value of 3 or 5 corneal endothelial cell counts was used as the statistical unit.

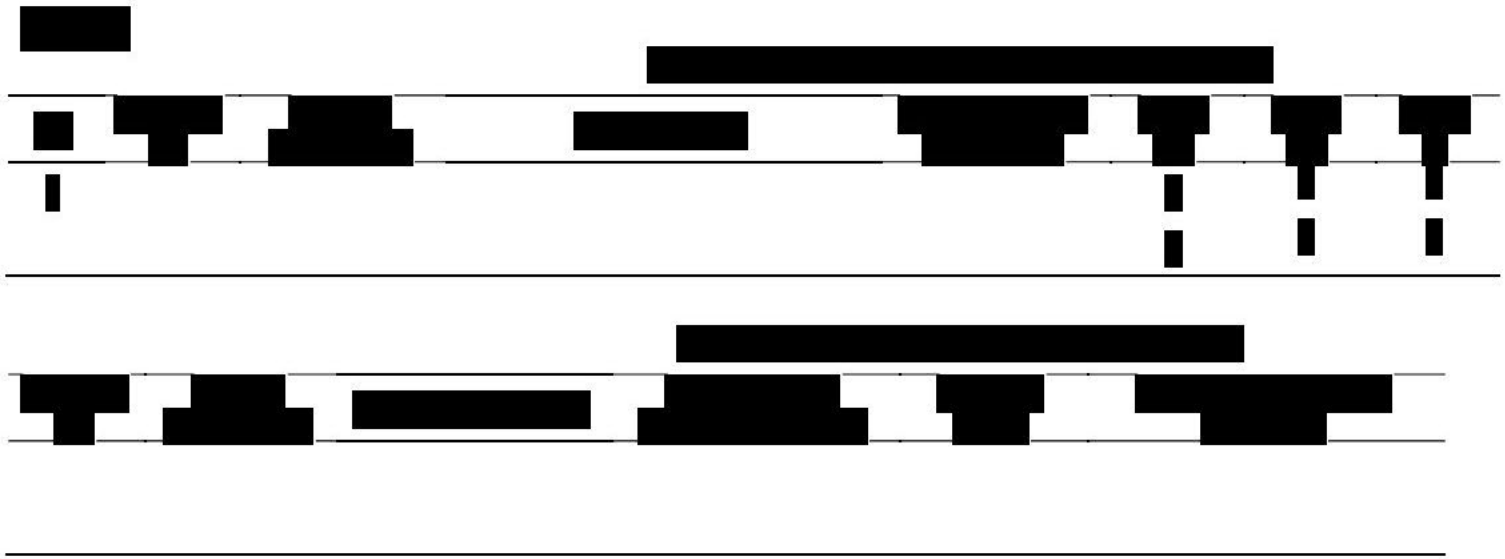


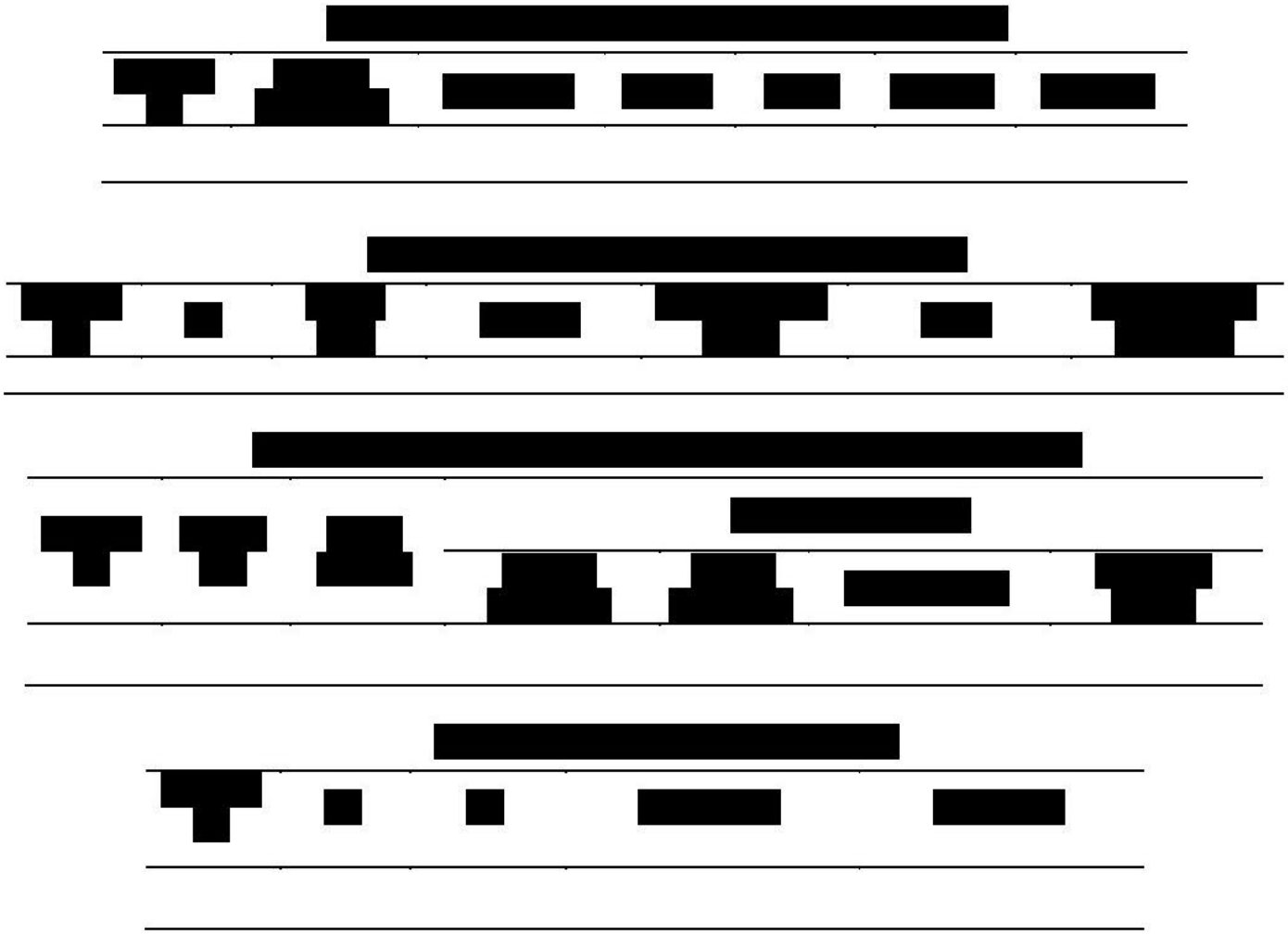






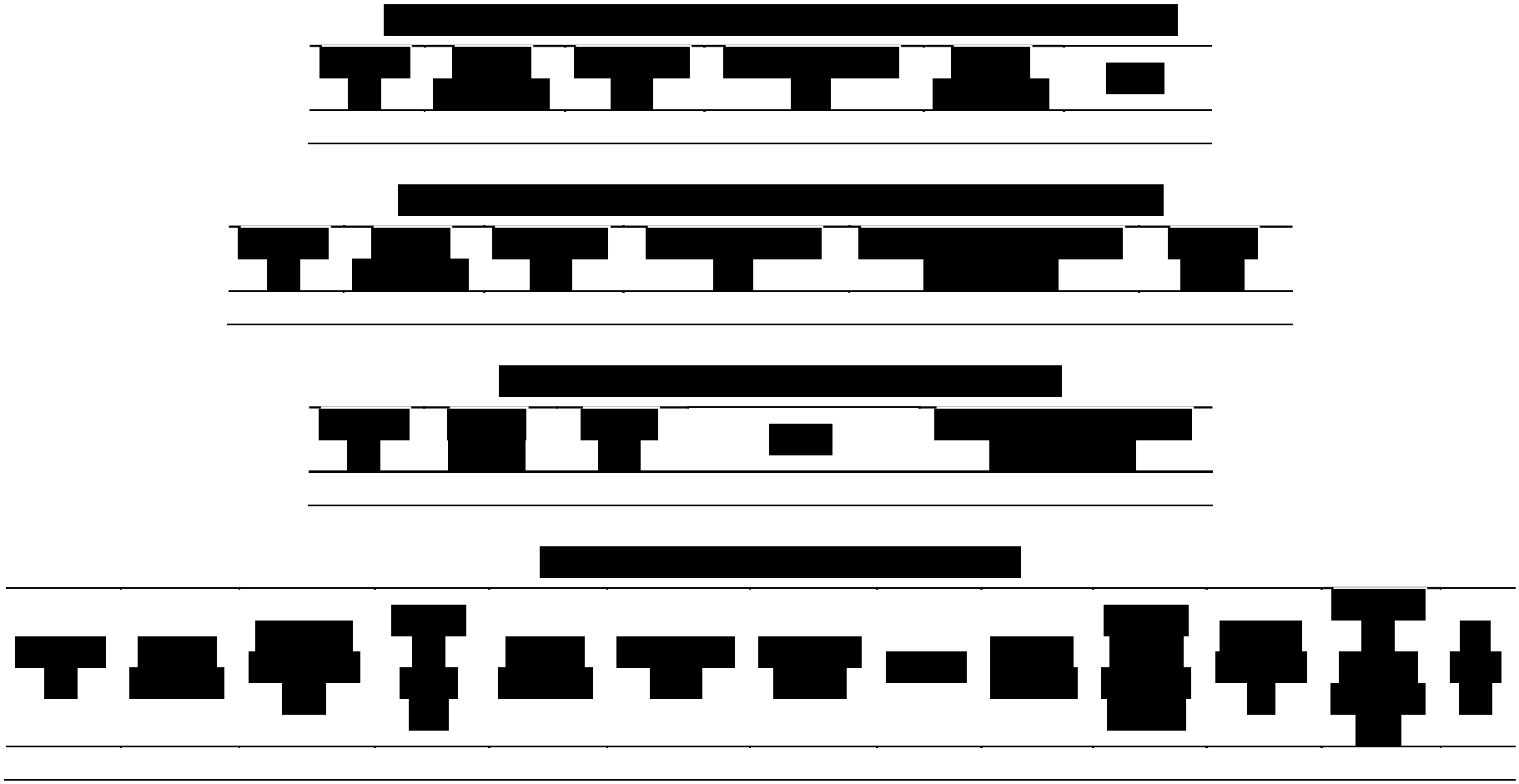


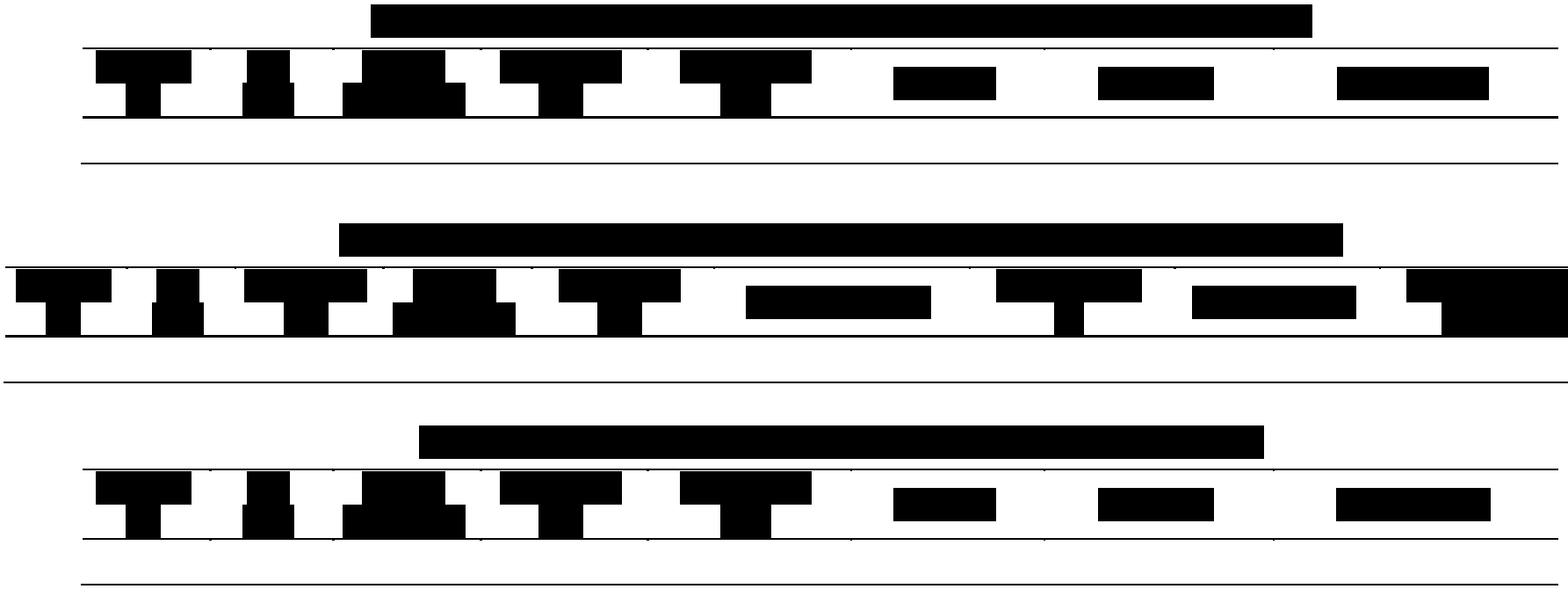












List 10.7.4.1-1 Subject adverse events (SS)

Screening No.	AE No.	Adverse events name	AE specific description	Notification time	occurrence time	End time	Degree	vest	Relation to surgery	Relation to the study device	If so, whether it is the expected AE	Study device measurements	Corrective treatment /record	SAE	SAE Classification	Whether to report to the regulatory authorities	Report date	The study was withdrawn due to A

List 10.7.4.1-2 Subject severe adverse events (SS)

Screening No.	SAE No.	SAE name	Ues date	Occurrence date	Date known to investigator	Date known to sponsor	SAE classification	Death date	Study device measurements	Vest	Relation to the device	Device deficiency	Whether expected	Other severe safety risk information	Wide range SAE and Other major safety issues	occurrence and possess situation	Risk control measures taken



