AEON Biopharma Inc.

ABP-19000

A Phase 2, Randomized, Double-Blind, Multicenter, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Intramuscular ABP-450 (prabotulinumtoxin A) Injection for the Treatment of Cervical Dystonia

22JUL2022

Statistical Analysis Plan Outline

Version 2.0

Prepared by:
[redacted]

[redacted]

TABLE OF CONTENTS

[redacted]

List of Abbreviations

ADA	anti-drug antibodies
AE	adverse event
ANCOVA	analysis of covariance
C-SSRS	Columbia-Suicide Severity Rating Scale
CD	Cervical dystonia
CGI-C	Clinical Global Impression of Change
CI	confidence interval
CRF	case report form
ECG	electrocardiogram
eICF	electronic informed consent form
EOS	end of study
FAS	Full Analysis Set
FEV1	forced expiratory volume in 1 second
FVC	forced vital capacity
ICF	informed consent form
ICH	International Conference on Harmonisation
IRT	interactive response technology
MedDRA	Medical Dictionary for Regulatory Activities
mFAS	Modified Full Analysis Set
PGI-C	Patient Global Impression of Change
PGI-S	Patient Global Impression of Severity
PPS	Per Protocol Analysis Set
PT	preferred term
OLE	open label extension
SAE	serious adverse event

SOC	system organ class
TEAE	treatment-emergent adverse events
TWSTRS	Toronto Western Spasmodic Torticollis Rating Scale
WHO	World Health Organization

1. Introduction

Cervical dystonia (spasmodic torticollis) is the most common form of focal dystonia, affecting the neck and shoulder muscles (Defazio 2004, Mittal 2019). Cervical dystonia is characterized by abnormal head and neck posture and involuntary head and neck movements. It is often associated with neck and shoulder pain.

Botulinum toxin A is considered first-line therapy for cervical dystonia, helping to improve pain, posture, and disability (Comella 2011, Simpson 2016, Mittal 2019). ABP-450 (prabotulinumtoxinA) is a toxin produced by *Clostridium botulinum*. It blocks neuromuscular transmission by binding to acceptor sites on motor nerve terminals, entering the nerve terminals, and inhibiting the release of acetylcholine. Blocking the release of acetylcholine plays a role in relaxing muscles by reducing muscle activity.

[redacted]

PrabotulinumtoxinA was evaluated in multiple non-clinical safety and toxicological tests to determine the pharmacologic and safety profile of the product in complying with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines/requirements for biologic products. [redacted]

[redacted]

PrabotulinumtoxinA has also been found to be non-inferior to onabotulinumtoxinA (BOTOX®) for the treatment of moderate to severe glabellar lines in adult patients and for upper limb spasticity in stroke patients (Nam 2015, Rzany 2019). The doses of ABP-450 used in the Phase 3 study for upper limb spasticity were similar to the doses of BOTOX® used (no significant differences were seen between the two groups) (Nam 2015).

This Phase 2, multicenter, randomized, double-blind, active- and placebo-controlled study aims to demonstrate the safety and efficacy of ABP-450 doses (low, medium, and high) compared with placebo in patients with cervical dystonia. The current Phase 2 study will help to determine appropriate doses of ABP-450 in this study population.

Clostridium botulinum toxins have become the standard of care for the treatment of patients with cervical dystonia. In addition to onabotulinumtoxinA, abobotulinumtoxinA, incobotulinumtoxinA, and rimabotulinumtoxinB have been approved for the treatment of patients with cervical dystonia. Even though these toxin products have been approved for the treatment of cervical dystonia and are the standard of care in patients with this condition, they do have significant risks associated with their use in these patients. The labels for all these products carry prominent warnings concerning their side effects, such as dysphagia and even death, if they are not carefully administered and the patient monitored while under treatment. Even so, the benefit for all these products is greater than the risks and that is why these products are the standard of care.

Clinical development of drugs has been impacted by the ongoing COVID-19 pandemic. The current study aims to implement several adjustments or mitigations to allow the study to continue despite pandemic-related disruption. To prioritize patient and site staff safety, several planned office visits have been converted to tele-visits to allow the required data collection to meet the study objectives

2. Objectives

2.1. Primary Objective

- To demonstrate the safety of a single treatment of ABP-450 (low, medium, or high dose) compared with placebo in the treatment of cervical dystonia

2.2. Secondary Objective

- To demonstrate the efficacy of a single treatment of ABP-450 (low, medium, or high dose) at Week 4 compared with placebo in the treatment of cervical dystonia

3. Investigational Plan

3.1. Overall Study Design and Plan

This is a Phase 2, multicenter, randomized, double-blind, placebo-controlled study of ABP-450 purified neurotoxin complex for the treatment of cervical dystonia.

Both previously treated patients and those who have never been exposed to botulinum toxin (naïve patients) will be eligible. Pre-treated patients must be stable responders who are receiving no more than 300 units of botulinum toxin type A or 750 units abobotulinumtoxinA. The last injection for those previously treated should be at least 16 weeks prior to treatment in ABP-19000. Botulinum toxin–naïve patients are defined as those not receiving treatment with a botulinum toxin in the head or neck.

Sixty Patients will be randomly assigned (ratio of 1:1:1:1) into 1 of 4 treatment arms: ABP-450 low dose (150 units), ABP-450 medium dose (250 units), ABP-450 high dose (350 units), or placebo. The investigator will be blinded to the dose level. The doses will be prepared to the same volume using appropriate dilution as per the dose level. The volume injected will be equivalent across the doses and placebo. To ensure balance across the treatment groups, randomization will be stratified by previous treatment with BOTOX® (BOTOX® naïve vs. previously treated with BOTOX® within 4-12 months prior to baseline). The safety and efficacy of the three dose cohorts of ABP-450 or placebo will be evaluated over a maximum of 20 weeks. At the completion of the Phase 2 study, all patients, irrespective of treatment group, will have the option to receive treatment with ABP-450 by rolling over into an open-label extension (OLE) study (ABP-19002).

[redacted]

[redacted]

This study will evaluate the safety and efficacy of ABP-450 or placebo over a maximum of 20 weeks. The primary objective will include evaluation of the safety of a single treatment of ABP-450 (low, medium, or high dose) compared with placebo. The secondary objective will include evaluation of the efficacy of a single treatment of ABP-450 (low, medium, or high dose) compared with placebo at Week 4.

[redacted]

3.2. Study Estimands

3.2.1. Primary Estimand

- Proportion of patients who would develop treatment-related serious adverse events (SAEs) during the first 20 weeks of a single treatment cycle when dosed with:
  - Placebo;
  - Low-dose ABP-450 (150 units);
  - Medium-dose ABP-450 (250 units);
  - High-dose ABP-450 (350 units); or
  - Any ABP-450 dose.

[redacted]

3.2.2. Secondary Estimands

- Mean difference in change in Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) total score from baseline to Week 4 for each of low, medium, and high doses of ABP-450 compared with placebo. This is the hypothetical estimand .
- Mean difference in change in the subscale scores of the TWSTRS (disability, severity, and pain) from baseline to Week 4 for each of low, medium, and high doses of ABP-450 compared with placebo. This is the hypothetical estimand.
- Mean difference in change in scores on the Clinical Global Impression of Severity (CGI-S) and Patient Global Impression of Severity (PGI-S) from baseline to Week 4 for each of low, medium, and high doses of ABP-450 compared with placebo. This is the hypothetical estimand.
- Mean difference in scores on the Clinical Global Impression of Change (CGI-C) and Patient Global Impression of Change (PGI-C) for each of low, medium, and

high doses of ABP-450 compared with placebo at Week 4. This is the hypothetical estimand.

- [redacted]
- [redacted]
- [redacted]
- [redacted]

3.3. Treatments

The four treatment groups are ABP-450 low dose (150 units), ABP-450 medium dose (250 units), ABP-450 high dose (350 units), and placebo. Investigational study drug is a *Clostridium botulinum* toxin type A

- Investigational study drug vials contain 100 units of lyophilized ABP-450
- Placebo vials contain sodium chloride for injection, USP, 0.9%, preservative-free

[redacted]

3.4. Dose Adjustment/Modifications

Investigational study drug dose modifications are not allowed.

4. General Statistical Considerations

The statistical principles applied in the design and planned analyses of this study are consistent with International Council for Harmonisation (ICH) E9 guidelines (ICH 1998).

[redacted]

[redacted]

Data summaries will be presented by treatment group unless otherwise specified. All efficacy analyses will be based upon the Full Analysis Set (mFAS, Section [redacted]), and all safety as well as demographic and baseline characteristic analyses will be based upon the Safety Analysis Set (Section 4.3.5). Additional analyses will be performed on selected populations as specified in the sections below.

[redacted]

[redacted]

[redacted].

4.1. Sample Size

Fifteen patients will be randomly assigned to each of four treatment arms (placebo, ABP-450 low dose, ABP-450 medium dose, and ABP-450 high dose) using a 1:1:1:1 ratio and therefore requiring a total of 60 patients. [redacted]

4.2. Randomization, Stratification, and Blinding

Approximately 60 patients will be randomly assigned (ratio of 1:1:1:1) into 1 of 4 treatment arms: ABP-450 low dose (150 units), ABP-450 medium dose (250 units), ABP-450 high dose (350 units), or placebo. [redacted]

[redacted]

The investigator will be blinded to the dose level. The volume injected will be equivalent across the doses and placebo. To ensure blinding, an appropriate and protocol-trained person at each site, such as a study nurse or other designee, will reconstitute investigational product vials in a manner blinded to the investigator and patient. [redacted] The designated person will then fill the syringe with the investigational product and give the filled syringe in a blinded fashion to the investigator. Appropriate spatial separation is required to ensure blinding. Blinding for the initial phase will be maintained throughout the study until the final assessment for the final patient has been entered into the database and the database lock has been performed.

If patients are unblinded during the study, they will be summarized in a table and presented in a listing.

4.3. Analysis Sets

4.3.1. Screened Set

The Screened Set will consist of all patients who signed informed consent and attended screening Visit 1.

4.3.2. Full Analysis Set (FAS)

The FAS will consist of all randomized patients who received investigational study drug. All analyses using the FAS will group patients according to randomized treatment.

4.3.3. Modified Full Analysis Set (mFAS)

The mFAS will consist of all patients in the FAS, but will exclude patients who have a [redacted]

[redacted] All analyses using the mFAS will group patients according to randomized treatment.

4.3.4. Per-Protocol Analysis Set (PPS)

The PPS will consist of all patients in the FAS who received placebo or ABP-450 (according to the set dose amount), but will exclude all patients who discontinued the study prior to Week 4 or had major protocol deviations which may affect evaluation of the TWSTRS assessment at Week 4. All analyses using the PPS will group patients according to actual treatment received.

4.3.5. Safety Analysis Set

The Safety Analysis Set will consist of all patients who received any investigational study drug. All analyses using the Safety Analysis Set will group patients according to treatment actually received.

5. Patient Disposition

5.1. Disposition

Patient disposition will be summarized categorically by treatment group and overall, and will include the number of patients that signed informed consent, the number of patients that were randomized, and the number and percentage of randomized patients in the FAS, mFAS, PPS, and Safety Analysis Sets. The reasons for study withdrawal will also be summarized categorically.

A listing of inclusion and exclusion criteria that were not met will be presented.

5.2. Protocol Deviations

Significant protocol deviations that may affect the evaluation of the TWSTRS assessment at Week 4 are considered major protocol deviations. Major protocol deviations will be summarized by treatment group and overall according to the following categories:

- [redacted]

A listing of patients with protocol deviations will also be provided.

6. Demographics and Baseline Characteristics

6.1. Demographics

Summaries of demographics and stratification factors will be summarized for patients in the mFAS and Safety Analysis Set by treatment group and overall. A listing will also be provided.

Demographic characteristics consist of:

- Age (continuous) in years
- Sex (Male, Female)
- Race (White, Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or Other pacific Islander, Other)
- Ethnicity (Hispanic or Latino, not Hispanic or Latino)

[redacted]

6.2. General Medical History

Medical History will be tabulated for the Safety Analysis Set by system organ class, preferred terms, and treatment groups and overall. Medical history will also be listed. Medical History will be coded by MedDRA version 23.1 (or later).

6.3. Inclusion and Exclusion Criteria

Inclusion and exclusion criteria not met by patients will be listed. Inclusion criteria, exclusion criteria, and rescreening instructions may be found in Protocol Sections 4.1.1, 4.1.2, and 4.1.3.

7. Treatments and Medications

7.1. Prior and Concomitant Medications

Prior and concomitant medications will include all prescription drugs, herbal products, vitamins, minerals, and over-the-counter medications. Prior and Concomitant medications will be coded by the World Health Organization (WHO) Drug Dictionary version 01SEP2020 (or later). Data summaries will be based on the Safety Analysis Set.

7.1.1. Prior Medications

Medications with a start date and/or stop date before the treatment start date will be considered prior medications. If start and stop dates are missing and the medication is not identified to be ongoing, the medication will be considered 'prior medications' if the data was entered at Visit 1 (Screening) or Visit 2 (Baseline). Prior medications will be summarized by treatment group and listed.

7.1.2. Concomitant Medications

Medications with a start or stop date on or after the treatment dosing date will be considered concomitant medications. All medications which are ongoing will be considered concomitant. Concomitant medications will be summarized by treatment group and listed.

[redacted]

7.2. Study Treatments

7.2.1. Extent of Exposure

Study treatment exposure will be summarized for all patients in Safety Analysis Set. The number of patients exposed to study treatment and the volume of injections will be summarized by treatment group. Drug accountability will also be listed.

7.2.2. Treatment Modifications

Investigational study drug dose modifications are not allowed.

8. Safety Analysis

Safety endpoints will be summarized with descriptive statistics. All safety summaries and analyses will be performed using the Safety Analysis Set.

Data will also be provided in listings.

8.1. Adverse Events

A treatment emergent adverse event (TEAE) is an adverse event (AE) with a start date on or after the date of treatment. The percentage of patients with TEAEs throughout the study will be summarized for ABP-450 (all doses together and separately) and placebo. [redacted]

- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

8.1.1. Primary Estimand

The primary estimand, the proportion of patients who develop treatment-related SAEs during the first 20 weeks of a single treatment, will be summarized by treatment group and across active treatment groups. [redacted] Treatment-related SAEs will be listed.

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	Treatment Policy

8.1.2. Overall Summary of Adverse Events

An overall summary of TEAEs will be tabulated by treatment group and across active treatment groups by providing the number and percent of patients who experience the following:

- [redacted]

8.1.3. Incidence of Adverse Events

The incidence and frequency of TEAEs will be summarized by SOC and PT. The number and percentage of patients and number of events will be presented for each treatment group and across active treatment groups. Adverse events will also be listed.

8.1.4. Relationship of Adverse Events to Study Drug

The investigator's assessment of an AE's relationship will be characterized using classification of Unrelated, Possible, Probable, and Definite. The incidence of TEAEs will be tabulated by SOC and PT and relationship to investigational study drug for each treatment group and across active treatment groups. Incidence will be based on the worst relationship within each level of summarization.

The incidence of related (possible, probable or definite) TEAEs from Week 1 to Week 20 will also be tabulated by SOC and PT.

8.1.5. Severity of Adverse Event

The severity, or intensity, of an AE refers to the extent to which an AE affects the patient's daily activities. The severity of the AE will be rated as mild, moderate, or severe. Changes in the severity of an AE will be captured in the CRF. The incidence of TEAEs will be tabulated by SOC and PT and severity for each treatment group and across active treatment groups (up to 20 weeks and 6 weeks separately). Incidence will be based on the worst severity within each level of summarization.

8.1.6. Serious Adverse Events

The incidence and frequency of serious TEAEs will be summarized by SOC and PT for each treatment group and across active treatment groups (up to 20 weeks and 6 weeks separately). SAEs will also be listed.

8.1.7. Relationship of Serious Adverse events

The incidence of serious TEAEs will be tabulated by SOC and PT and relationship to investigational study drug for each treatment group and across active treatment groups (up to 20 weeks and 6 weeks separately). Incidence will be based on the worst relationship within each level of summarization.

8.1.8. Adverse Events Leading to Study Withdrawal

The incidence of TEAEs leading to study withdrawal will be summarized for each treatment group and across active treatment groups by SOC and PT.

8.1.9. Severity of Serious Adverse Events

The incidence of serious TEAEs will be tabulated by SOC, PT, and severity for each treatment group and across active treatment groups. Incidence will be based on the worst severity within each level of summarization.

8.1.10. Suspected Unexpected Serious Adverse Events

A suspected unexpected serious adverse event (SUSAR) is defined as an AE, the nature or severity of which is not consistent with the applicable product information (e.g., investigator's brochure for an unapproved investigational medicinal product). The incidence of SUSARs will be summarized for each treatment group and across active treatment groups by SOC and PT.

8.1.11. Non-Serious Adverse Events of Special Interest

Adverse events potentially suggestive of distant spread of toxin effects are listed in Appendix 14.9. The incidence of non-serious AEs of special interest will be summarized for each treatment group and across active treatment groups by SOC and PT.

8.1.12. Death

A listing of patient deaths will be presented.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

8.2.5. Pregnancy

A urine pregnancy test will be performed at the Screening visit (Visit 1), Visit 2 (Day 1), and EOS (Week 20). Pregnancy test data will be provided in a listing.

8.3. Vital Sign Measurements

Vital sign measurements will be performed at Screening (Visit 1), Visit 2 (Day 1), Visit 4 (Week 4), and EOS (Week 20). Vital signs include heart rate, respiratory rate, blood

pressure, oxygen saturation, and body temperature. The patient's height and weight will be assessed at the Baseline visit.

Mean change from baseline in vital signs will be summarized by scheduled visit for each treatment group and across active treatment groups. A listing of vital signs will also be provided.

[redacted]

[redacted]

8.7. Columbia-Suicide Severity Rating Scale (C-SSRS)

The C-SSRS will be performed at Screening (Visit 1), Visit 4 (Week 4), Visit 6 (Week 8), Visit 8 (Week 12), Visit 10 (Week 16), and EOS (Week 20). The C-SSRS was developed by the United States FDA in 2012 for measuring suicidal ideation and behavior in clinical trials (Posner et al. 2011). The C-SSRS was designed to distinguish the domains of suicidal ideation and suicidal behavior. Four constructs are measured. The first is the severity of ideation (hereafter referred to as the "severity subscale"), which is rated on a 5-point ordinal scale in which 1 = wish to be dead, 2 = non-specific active suicidal thoughts, 3 = suicidal thoughts with methods, 4 = suicidal intent, and 5 = suicidal intent with plan. The second is the intensity of ideation subscale (hereafter referred to as the "intensity subscale"), which comprises 5 items, each rated on a 5-point ordinal scale: frequency, duration, controllability, deterrents, and reason for ideation. The third is the behavior subscale, which is rated on a nominal scale that includes actual, aborted, and interrupted attempts; preparatory behavior; and non-suicidal self-injurious behavior. The fourth is the lethality subscale, which assesses actual attempts; actual lethality is rated on a 6-point ordinal scale, and if actual lethality is zero, potential lethality of attempts is rated on a 3-point ordinal scale (Posner et al. 2011).

The frequency and percentage of C-SSRS responses will be tabulated by visit for each treatment group and across active treatment groups. The C-SSRS responses will also be provided in a listing.

8.8. Sensitivity Analyses

[redacted]

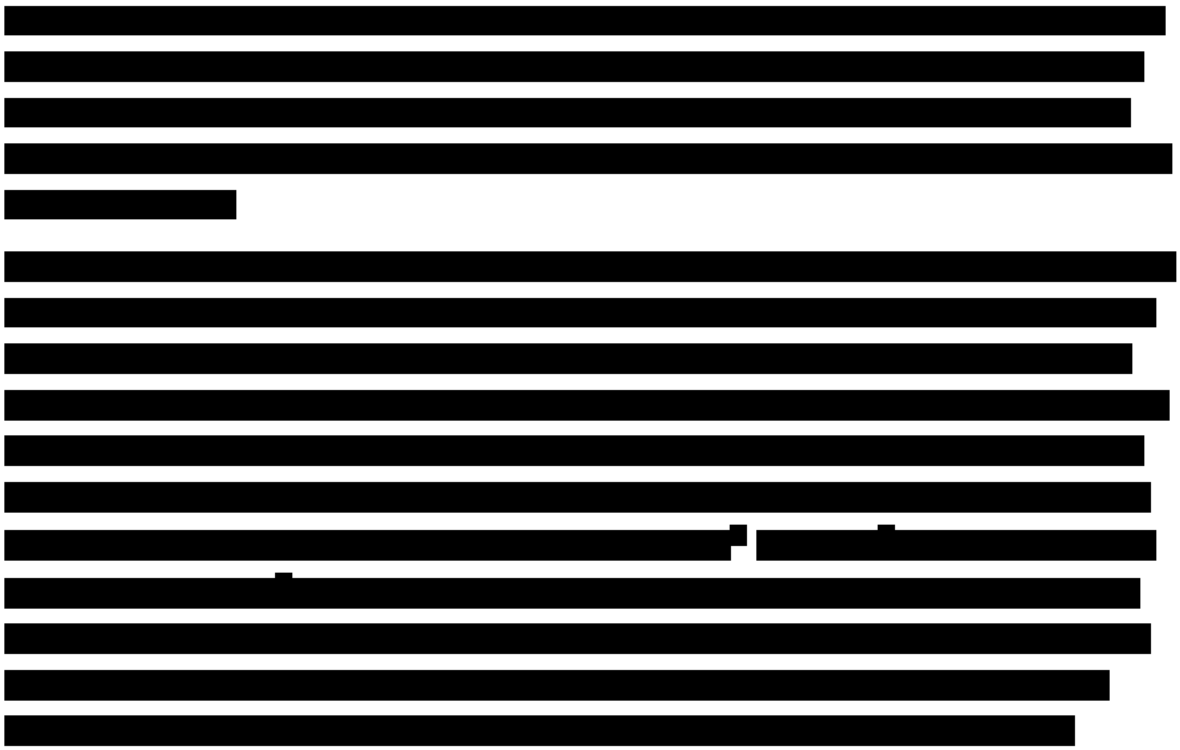
9. Efficacy Analysis

Unless otherwise indicated, all inferential efficacy analyses will include all patients in the mFAS. The PPS will also be applied to analyses and summaries on TWSTRS scores. Missing data imputation will be performed as described in each section. Visit windows for efficacy analyses are described in Appendix 14.2. Efficacy analyses will be tabulated by treatment group. Figures will be produced for measures over time.

9.1. Secondary Estimands

9.1.1. TWSTRS

Most studies leading to the approval of currently available botulinum neurotoxins have used the TWSTRS scale as the primary efficacy measure (Espay 2018, Fernandez 2013). The standard TWSTRS is a comprehensive scale that comprises three subsets to assess motor severity, pain, and disability (Comella 2016). The motor severity subscale consists of 10 items, with variable scaling and weighting. It also includes a disability subscale with 6 items and a pain scale with 3 items. The total score is the sum of each of the subscales.



[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	Hypothetical

Mean difference in change in the subscale scores of TWSTRS (disability, severity, and pain) from baseline to Week 4 for each of low, medium, and high doses of ABP-450 compared to placebo will also be analyzed [redacted]

Summary statistics for change from baseline of TWSTRS total score and subscale scores (disability, severity, and pain) every 4 weeks will be tabulated by treatment group and displayed in figures over time. [redacted]

Summary statistics for time to loss of ≥ 80% of peak treatment effect for patients dosed on ABP-450 will be tabulated by treatment group. [redacted]

[redacted]

[redacted]

9.1.2. CGI-S

CGI-S enables the clinician to rate the severity of the patient's illness, relative to their past experience with patients who have the same diagnosis, on a 7-point scale ranging from "normal" to "among the most extremely ill patients" (Guy 1976). In this study, a 4-point scale will be used (see Appendix 0).

CGI-S scores will be measured at Baseline Visit 2 (Day 1), Visit 4 (Week 4), Visit 6 (Week 8), Visit 8 (Week 12), Visit 10 (Week 16), and EOS (Week 20). [redacted] A listing of CGI-S scores will be provided.

[redacted]

9.1.3. PGI-S

The PGI-S is a 1-item global index with a 7-day recall period that enables the patient to rate their impression of disease severity via a 4-point scale ranging from "normal" to "severely ill" (Guy 1976). The 4-point PGI-S scale which will be used in this study is described in Appendix 14.7.

PGI-S scores will be measured at Baseline Visit 2 (Day 1), Visit 4 (Week 4), Visit 6 (Week 8), Visit 8 (Week 12), Visit 10 (Week 16), and EOS (Week 20). The mean change from baseline from Week 4 in PGI-S score will be analyzed [redacted]

9.1.4. CGI-C

CGI-C is a 7-point scale ranging from "very much improved" to "very much worse" (Guy 1976) based on the physician's perception of the patient's health status. The 7-point CGI-C scale which will be used in this study is described in Appendix 0. CGI-C scores will be measured at Visit 4 (Week 4), Visit 6 (Week 8), Visit 8 (Week 12), Visit 10 (Week 16), and EOS (Week 20). The mean CGI-C score will be analyzed [redacted]

[redacted]

[redacted] A listing of CGI-C scores will be provided.

9.1.5. PGI-C

The PGI-C enables the patient to rate changes in their perception of their general health status over the duration of the assessment via a 7-point scale ranging from "very much improved" to "very much worse" (Fischer 1999). The PGI-C recall period varies between studies as it relates to the change from the study start to the last assessment. The 7-point PGI-C scale which will be used in this study is described in Appendix 14.7.

PGI-C scores will be measured at Visit 4 (Week 4), Visit 6 (Week 8), Visit 8 (Week 12), Visit 10 (Week 16), and EOS (Week 20). The mean PGI-C score will be analyzed [redacted] A listing of PGI-C scores will be provided.

9.2. Sensitivity Analyses

Sensitivity analysis will be performed for mean difference in TWSTRS total score from baseline to Week 4 for each low, medium, and high doses of ABP-450 compared to placebo, [redacted]. Similarly, mean difference in change in the subscale scores of TWSTRS (disability, severity, and pain) from baseline to Week 4 for each low, medium, and high doses of ABP-450 compared with placebo will be made, [redacted]

Additional sensitivity analyses will be performed for mean difference in TWSTRS total score (and subscale scores) from baseline to Week 4 for each low, medium, and high doses of ABP-450 compared to placebo for the FAS using the same analysis described in Section 9.1.1.

[redacted]

9.3. Dysphagia Severity Scale

[redacted]

[redacted]Dysphagia scores will be listed.

10. Interim Analysis

No interim analyses are planned.

11. Changes in the Planned Analysis

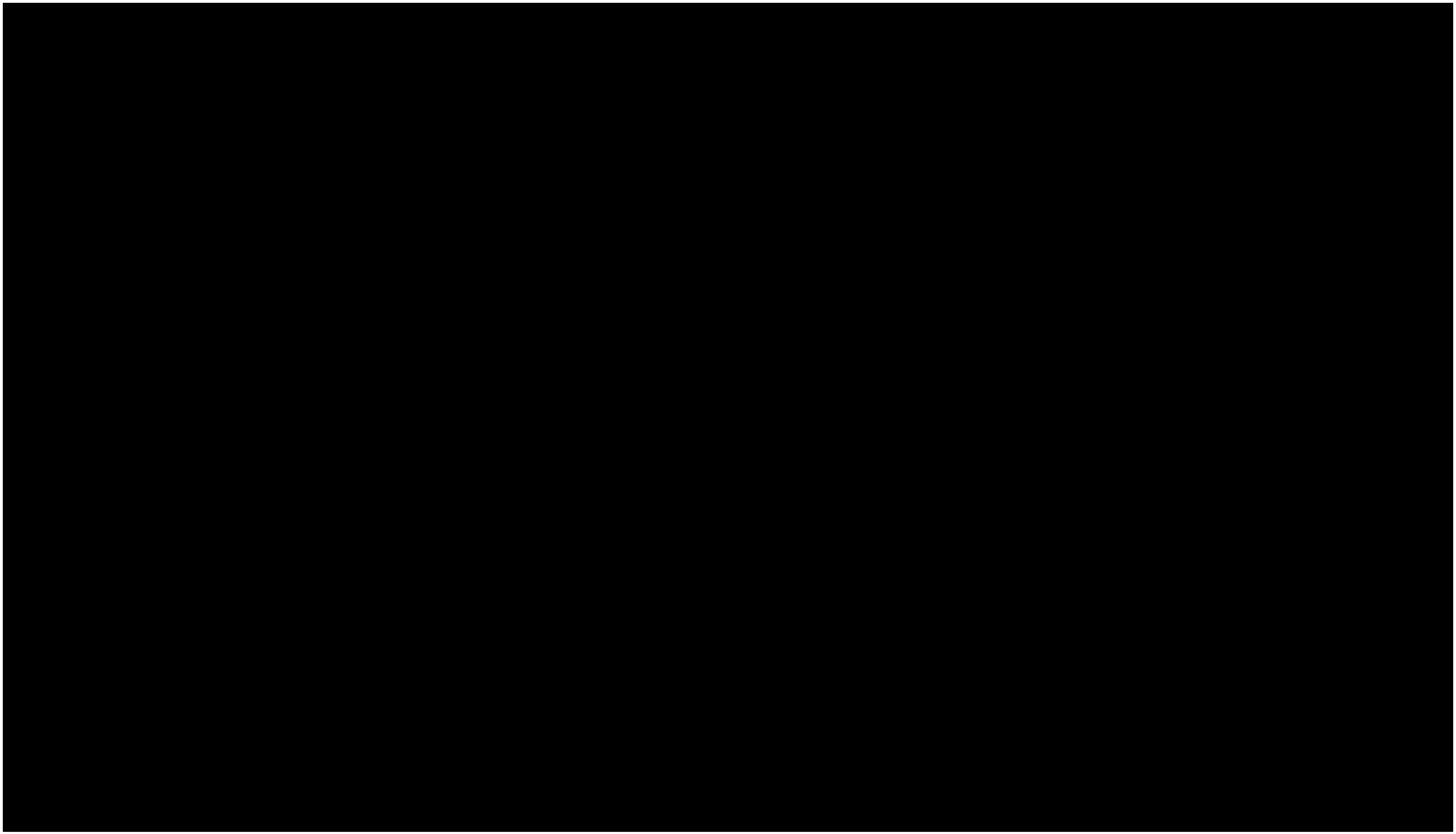
[redacted]

12. References

[redacted]

[redacted]

[redacted]



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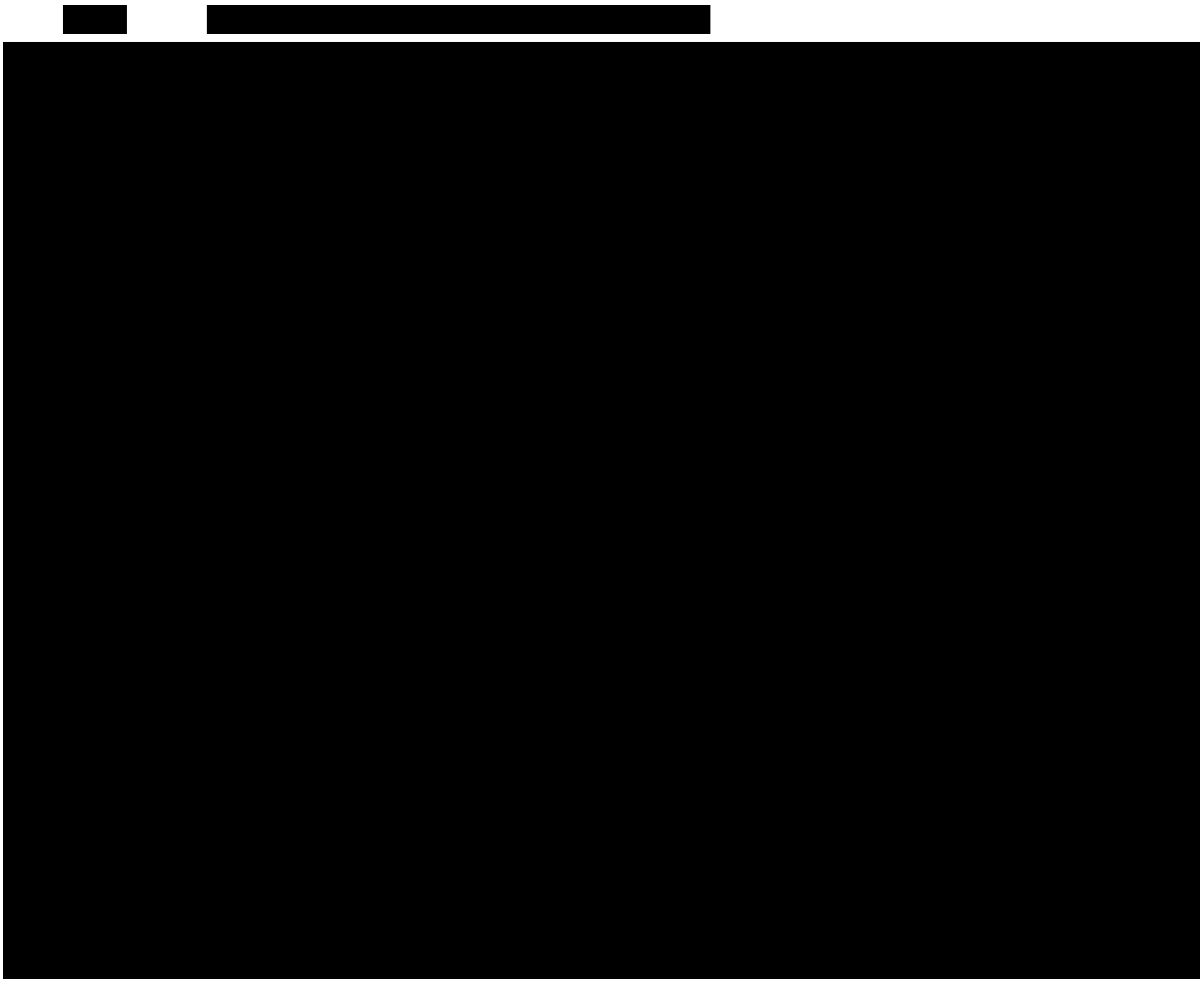

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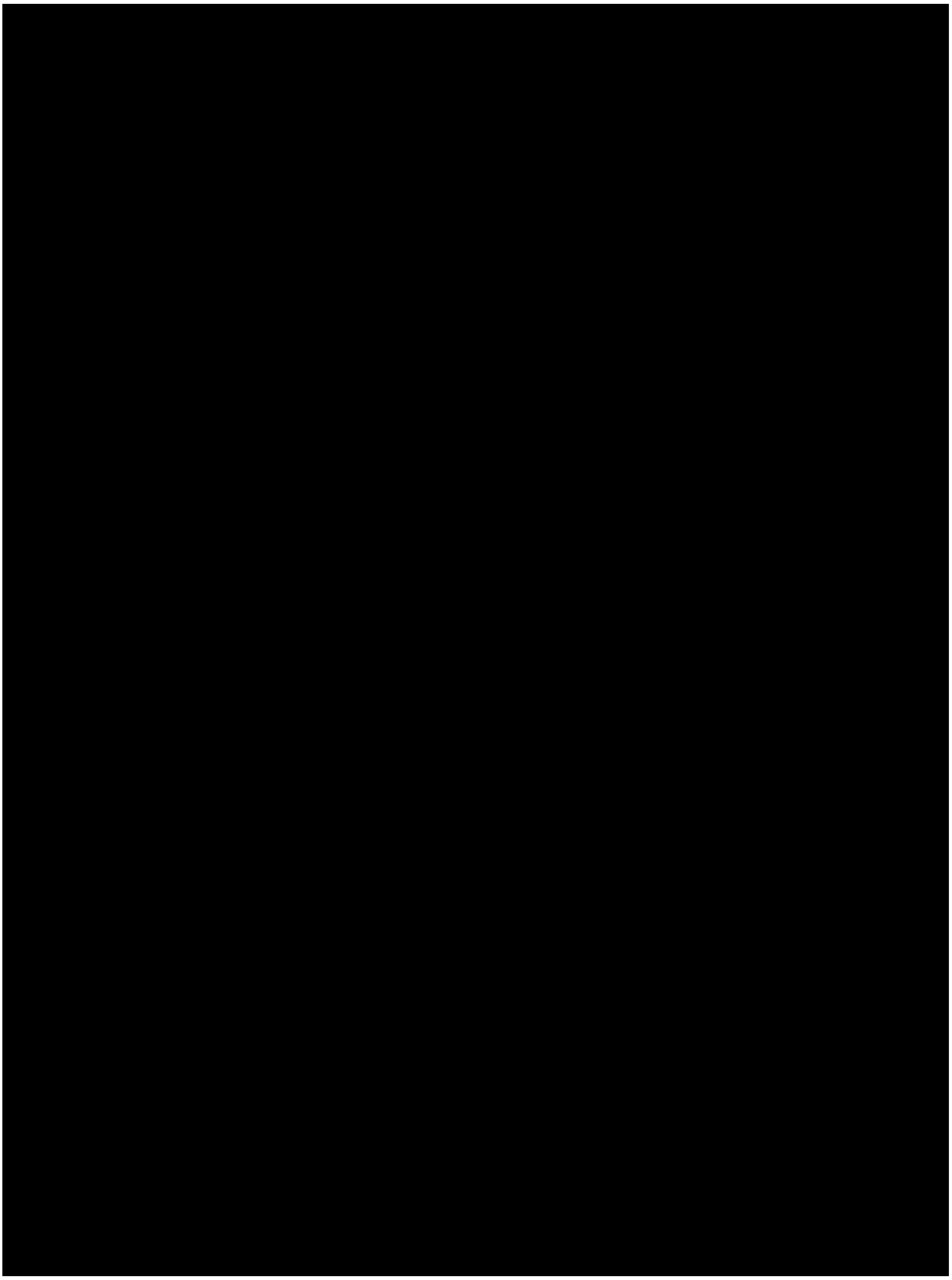

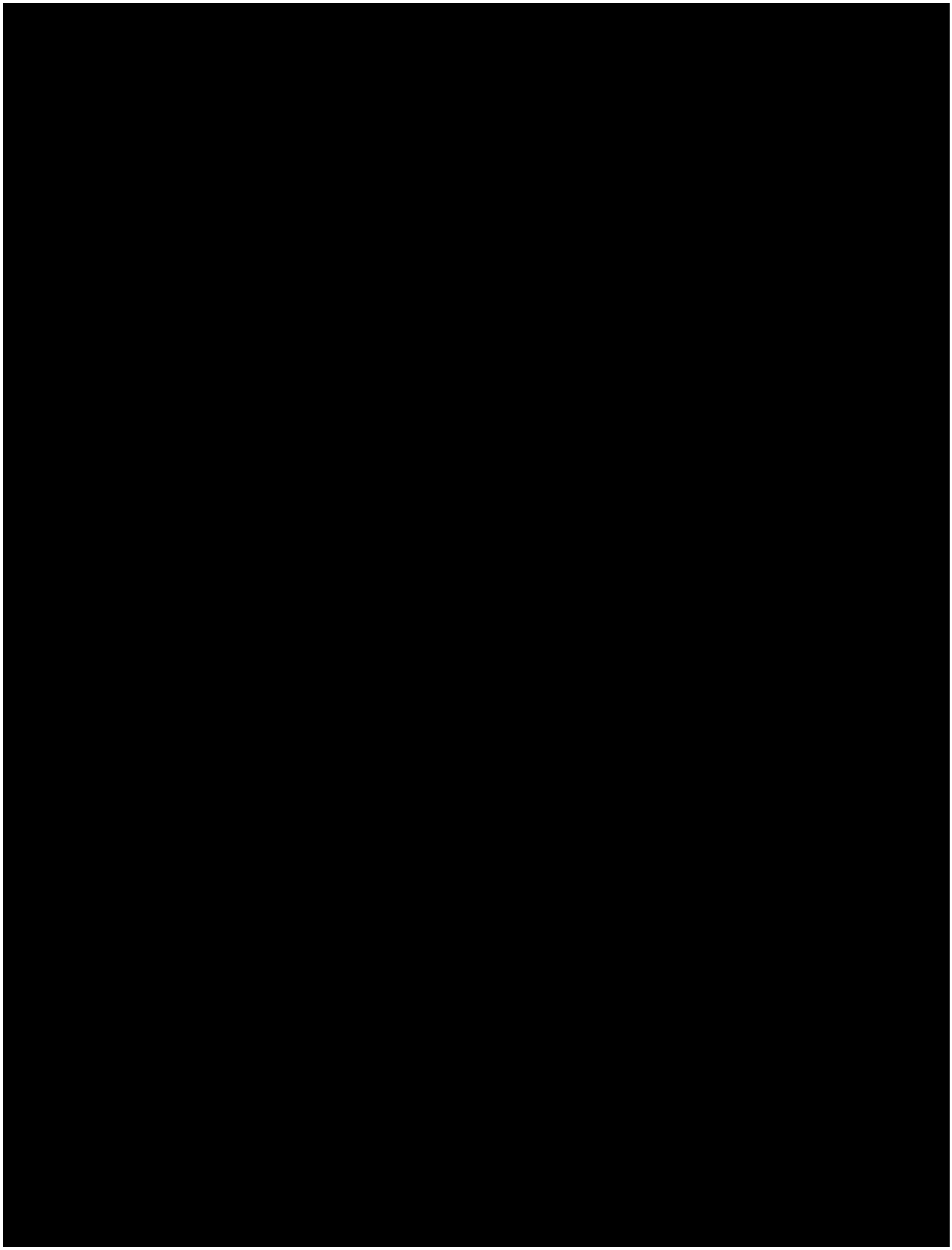

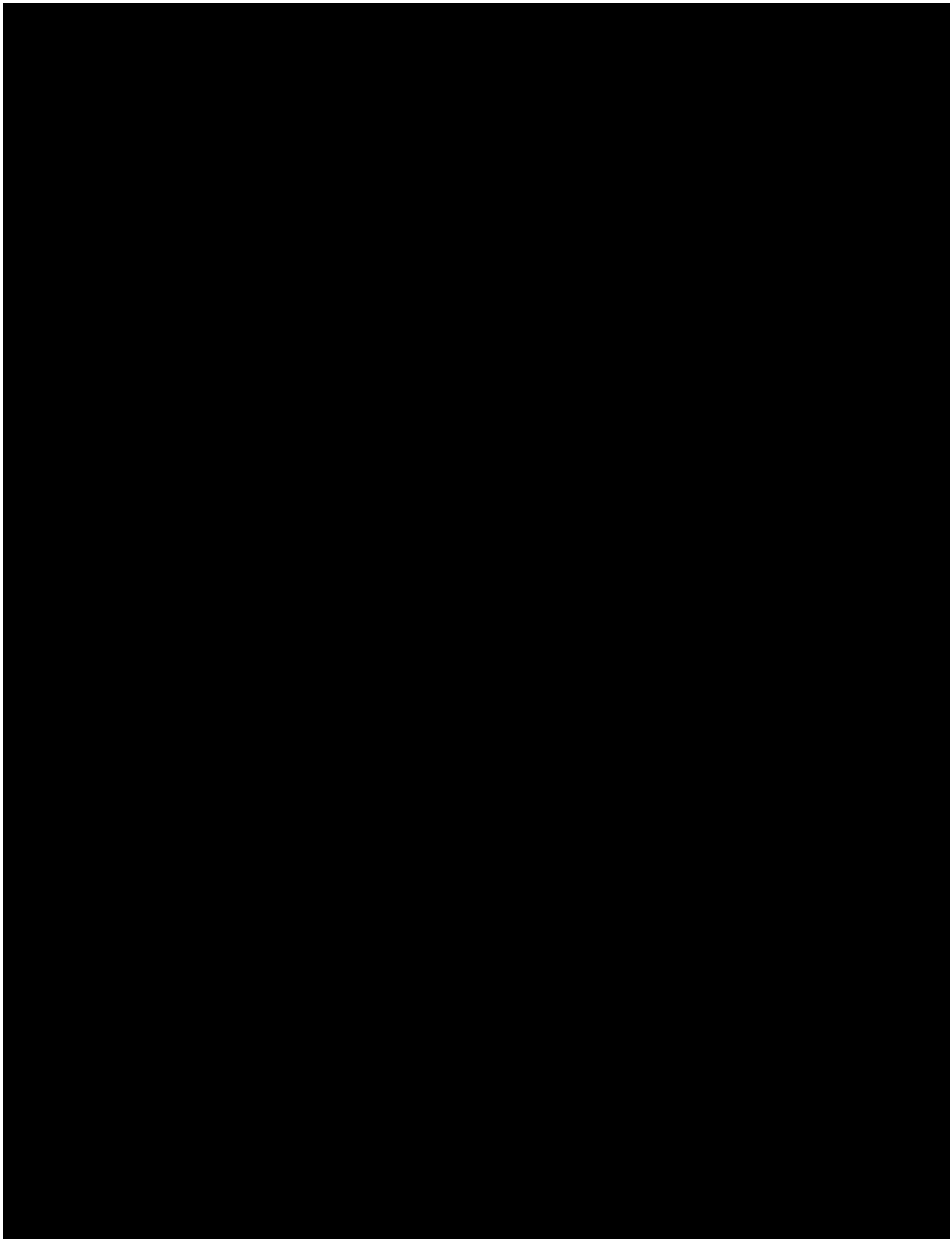

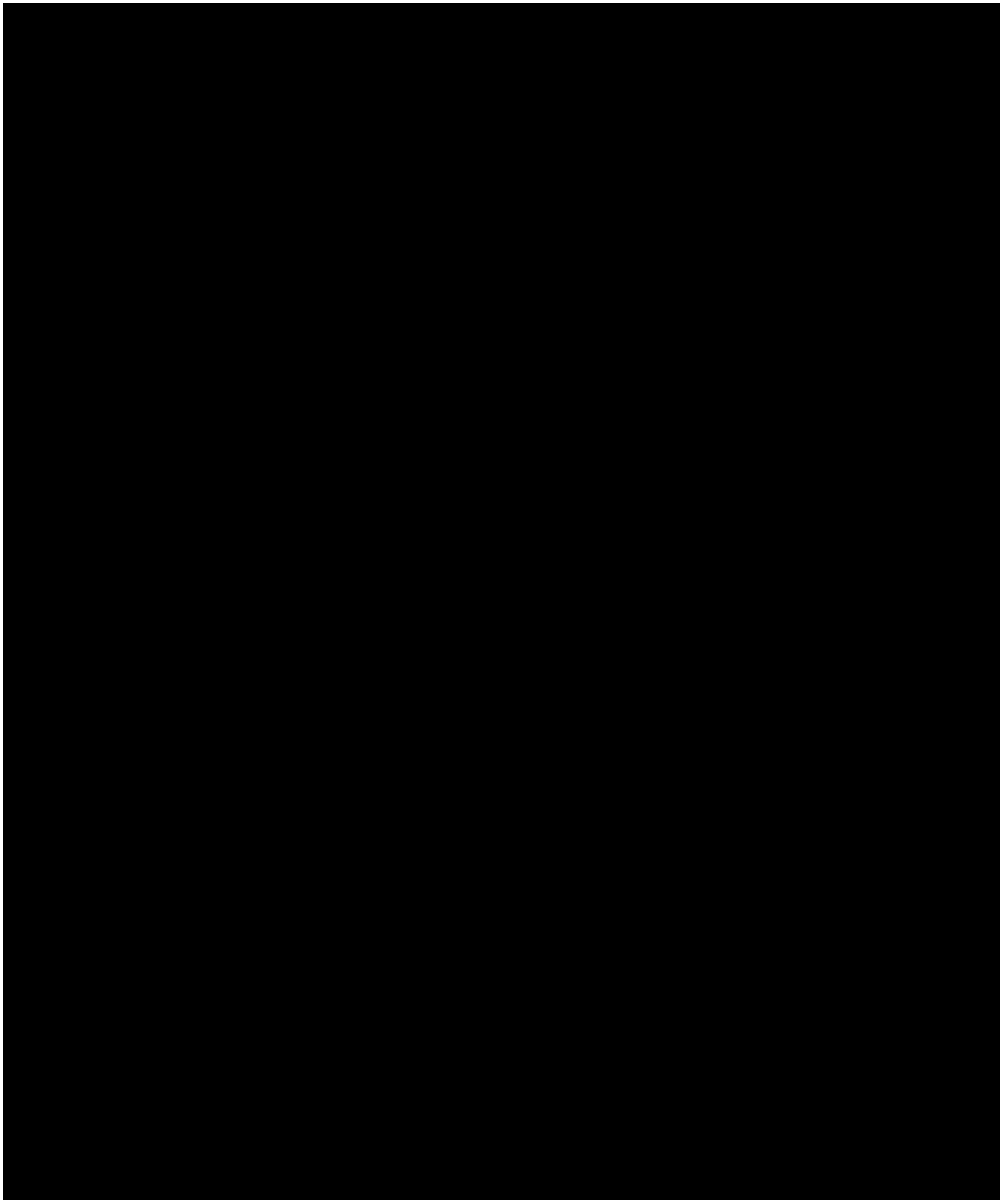

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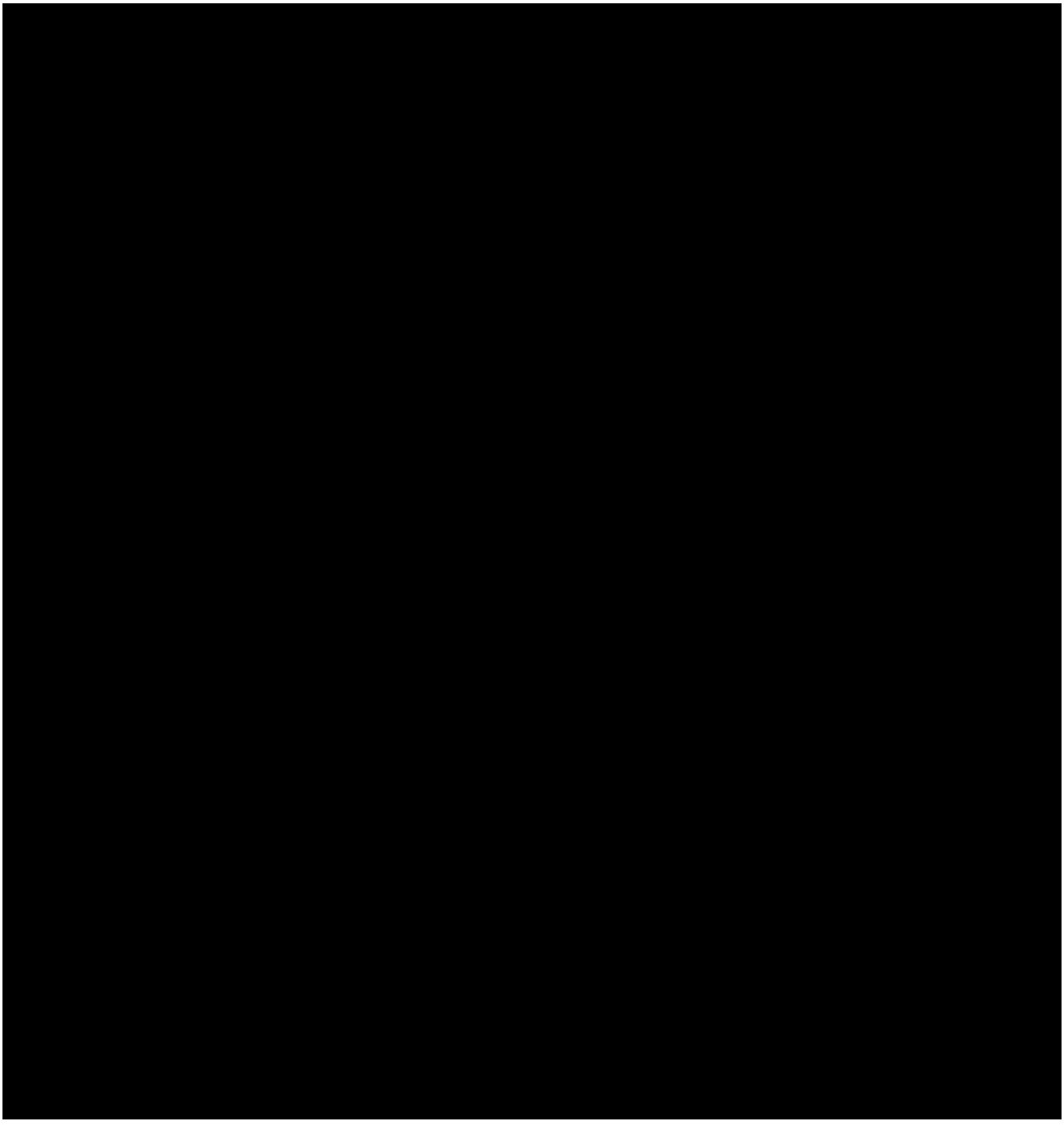

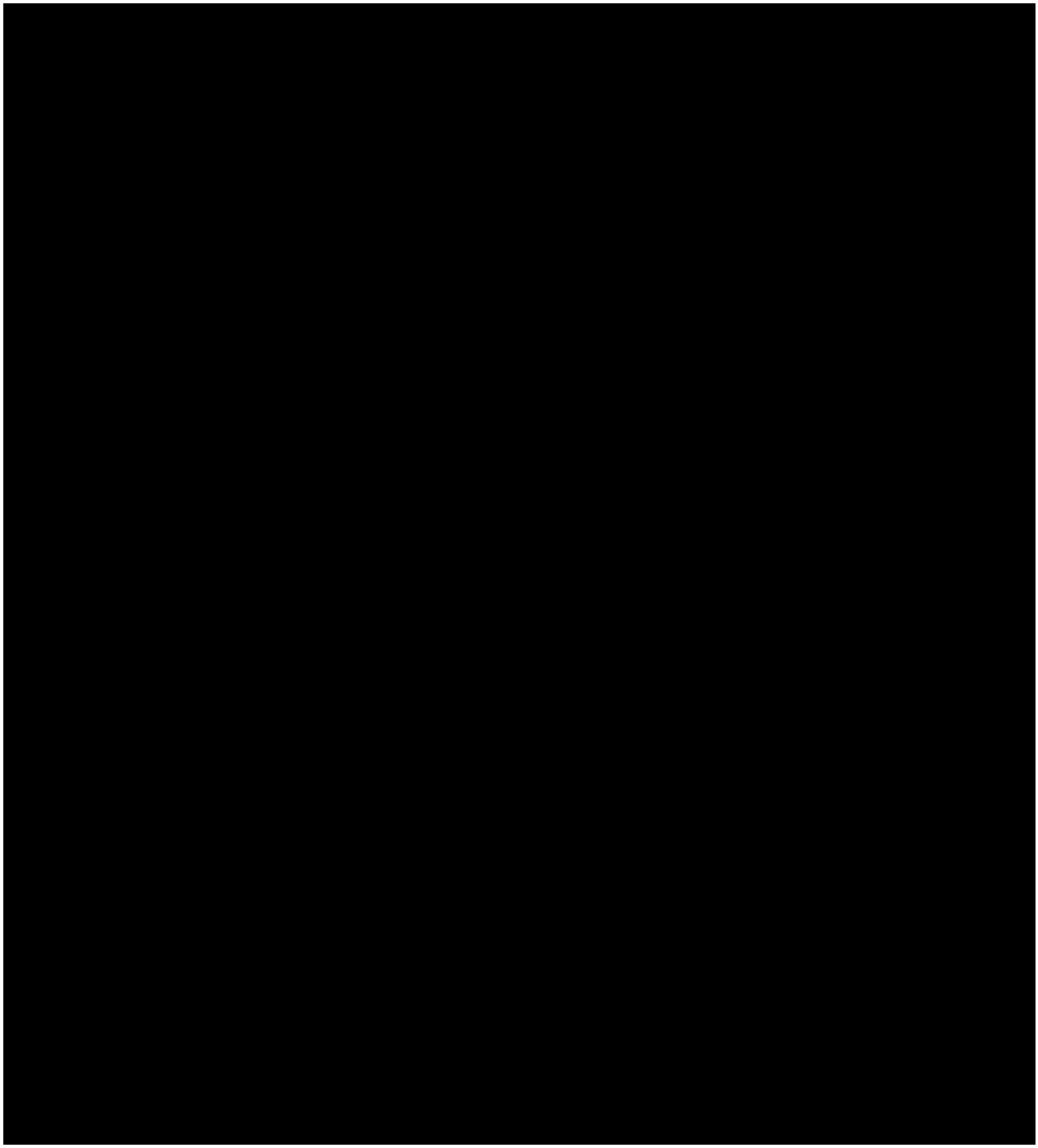

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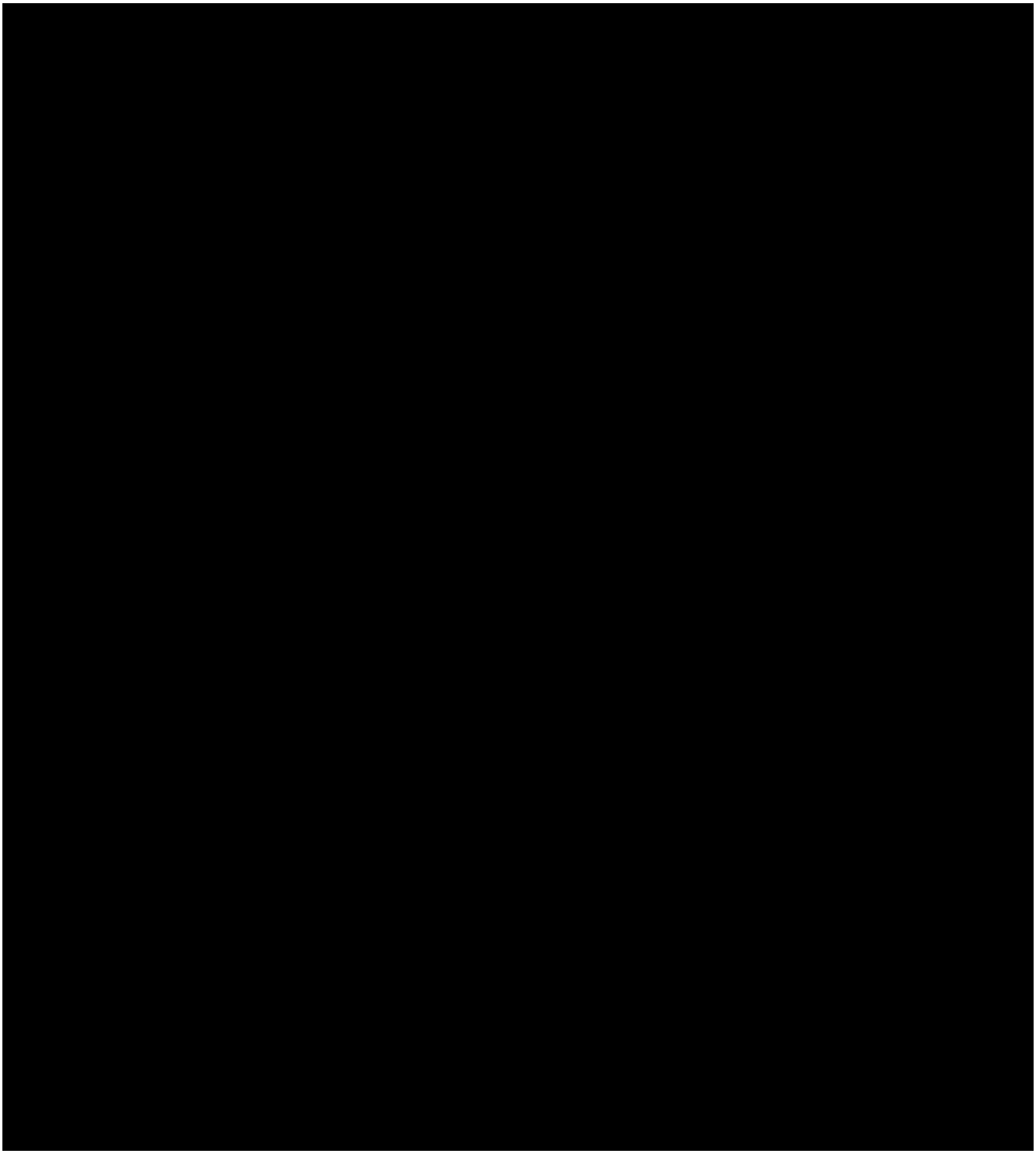

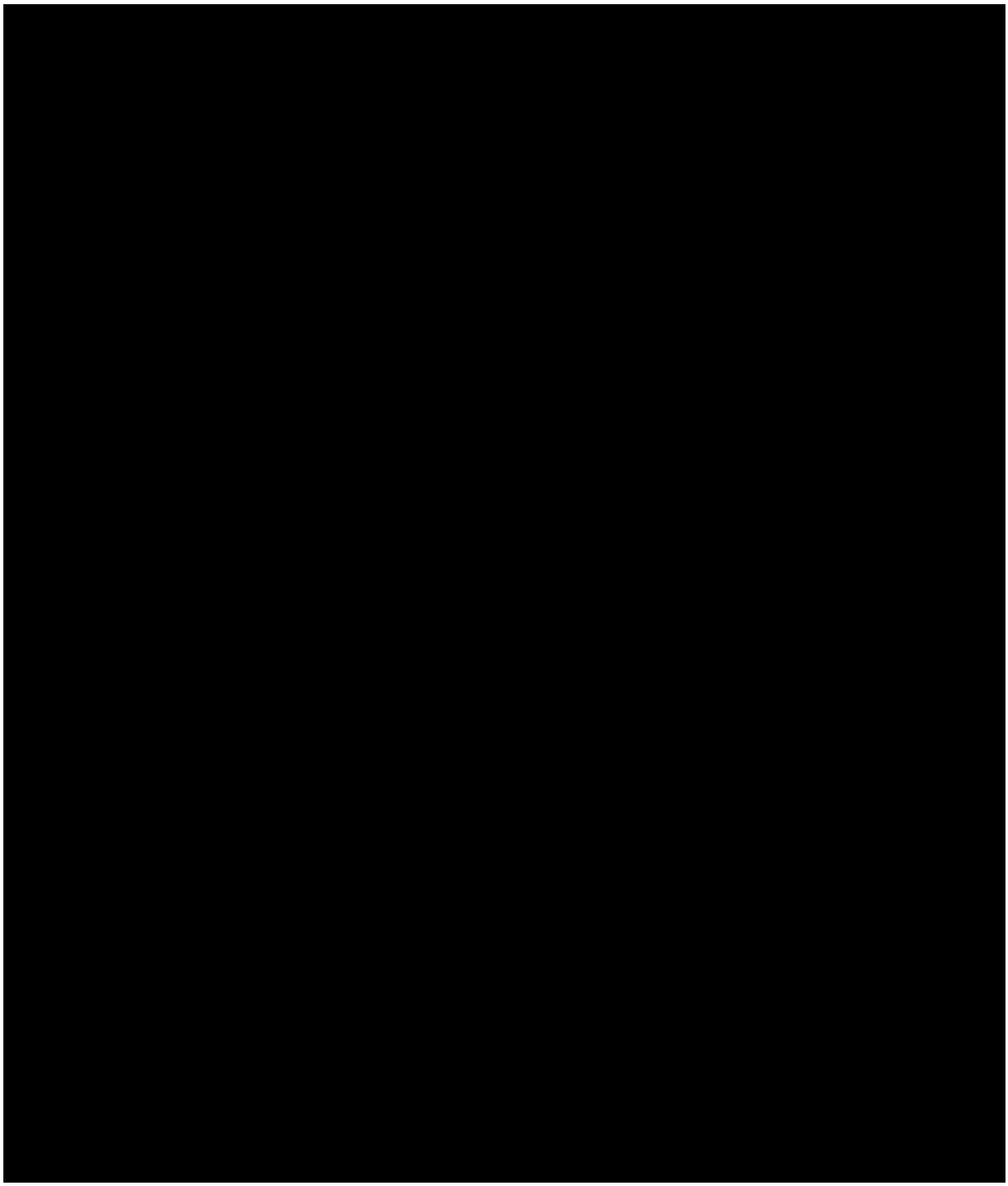

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