

PRVNÍ DODATEK KE SMLouvĚ O KLINICKÉM HODNOCENÍ

První dodatek („**Dodatek**“) ke Smlouvě o klinickém hodnocení („**Smlouva**“), uzavřené s účinností od 5. června 2020, mezi **Fakultní nemocnice Ostrava**, 17. Listopadu 1790, 708 52 Ostrava - Poruba, Česká republika, IČ: 008 43 989, DIČ: CZ00843989, Zřizovací listina MZ ČR ze dne 25. listopadu 1990 č.j. OP-054-25.11.90, zastoupenou MUDr. Jiřím Havrlantem, MHA, ředitelem. Ve věcech tohoto dodatku je oprávněn jednat a podepisovat: doc. et doc. MUDr. Petr Vávra, Ph.D., náměstek ředitele pro vědu, výzkum a výuku („**Zdravotnické zařízení**“) a **prof. MUDr. Romana Hájka, CSc.**, [REDACTED] („**Hlavní zkoušející**“) a **AbbVie, s. r. o.**, Metronom Business Center, Bucharova 2817/13, Stodůlky, 158 00 Praha 5, Česká republika, IČ: 24148725, DIČ: CZ24148725, zastoupené Mgr. Janem Balzerem, Country Operations Manager, na základě plné moci („**AbbVie**“) na poskytování služeb uvedených v Protokolu č. **M19-708** s názvem „**Randomizovaná, otevřená, multicentrická studie fáze 3 s 2 rameny hodnotící venetoclax a azacitidin oproti nejlepší podpůrné péči v udržovací léčbě u pacientů s akutní myeloidní leukémií při první remisi po konvenční chemoterapii (VIALE-M)**“.

S ohledem na řádné plnění tohoto Dodatku a v souladu s podmínkami Smlouvy, se smluvní strany dohodly pozměnit Smlouvu následovně:

1. Rozpočet stanovený v Příloze A Smlouvy se zrušují v celém svém rozsahu a nahrazují se příloženými Přílohou A.

Pojmy, jež zde nejsou definovány jinak, mají stejný význam, který je jim připisován ve Smlouvě. Kromě podmínek, které se výslovně změnily tímto Dodatkem, zůstávají všechny ostatní podmínky této Smlouvy v plné platnosti a účinnosti během trvání této Smlouvy.

Tento Dodatek je sepsán ve třech vyhotoveních v českém a anglickém jazyce. V případě rozporu

FIRST AMENDMENT TO THE CLINICAL STUDY AGREEMENT

First Amendment (the „**Amendment**“) to that certain Clinical Study Agreement („**Agreement**“) effective 5 June 2020, between **Fakultní nemocnice Ostrava**, 17. Listopadu 1790, 708 52 Ostrava - Poruba, Czech Republic, ID: 008 43 989, VAT ID: CZ00843989, Letter of Establishment by Ministry of Health of Czech Republic, dated as of 25 November 1990, reg.no. OP-054-25.11.90, represented by MUDr. Jiří Havrlant, MHA, Director. Doc. et doc. MUDr. Petr Vávra, Ph.D., Deputy Director for Science, Research and Education of the Institution is authorized to execute this Amendment on behalf of the Institution (the „**Institution**“) and [REDACTED] (the „**Principal Investigator**“) and **AbbVie s.r.o.**, Metronom Business Center, Bucharova 2817/13, Stodůlky, 158 00 Praha 5, Czech Republic, ID: 24148725, VAT ID: CZ24148725, represented by Mgr. Jan Balzer, Country Clinical Operations Manager, upon power of attorney („**AbbVie**“) for services relating to Protocol No. **M19-708** entitled „**Randomized, Open-label, 2-Arm, Multicenter, Phase 3 Study of Venetoclax and Azacitidine Versus Best Supportive Care as Maintenance Therapy for Patients with Acute Myeloid Leukemia in First Remission After Conventional Chemotherapy (VIALE-M)**“.

Subject to the full execution of this Amendment and in accordance with the terms of the Agreement, the parties hereby agree to amend the Agreement, as follows:

1. The Budget set forth in Exhibit A of the Agreement shall be deleted in its entirety and replaced with the attached Exhibit A.

Terms not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement. Except as specifically amended by this Amendment, all other terms and conditions of the Agreement shall continue in full force and effect during the term of the Agreement.

This Amendment has been made in three counterparts in Czech and English language. In the event of conflict

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obou jazykových verzí je rozhodující české znění Dodatku. Tento Dodatek nabývá platnosti okamžikem podpisu všech smluvních stran a účinnosti okamžikem zveřejnění dle zákona č. 340/2015 Sb., o registru smluv. NA DŮKAZ ČEHOŽ každá smluvní strana prostřednictvím svých řádně zmocněných zástupců uvedla tuto smlouvu v platnost svým podpisem. AbbVie s.r.o. By/Podepsal: _____ Name/Jméno: Mgr. Jan Balzer Title/Funkce: Country Clinical Operations Manager Upon the power of attorney/Na základě plné moci Date/Datum: _____	between both language versions, Czech language version of the Amendment shall prevail. This Amendment shall become executed upon its signing by all Parties and effective as of the day of its publishing in Contracts Registry, in accordance with Act no. 340/2015 Coll., on Contracts Registry, as amended. IN WITNESS WHEREOF, each of the parties has caused this Amendment to be executed by its authorized representative in its name and on its behalf. Fakultní nemocnice Ostrava By/Podepsal: _____ Name/Jméno: doc. et doc. MUDr. Petr Vávra, Ph.D. Title/Funkce: Deputy Director for Science, Research and Education / náměstek ředitele vědu, výzkum a výuku Date/Datum: _____ _____ By/Podepsal: _____ Title/Funkce: Principal Investigator / Hlavní zkoušející Date/Datum: _____
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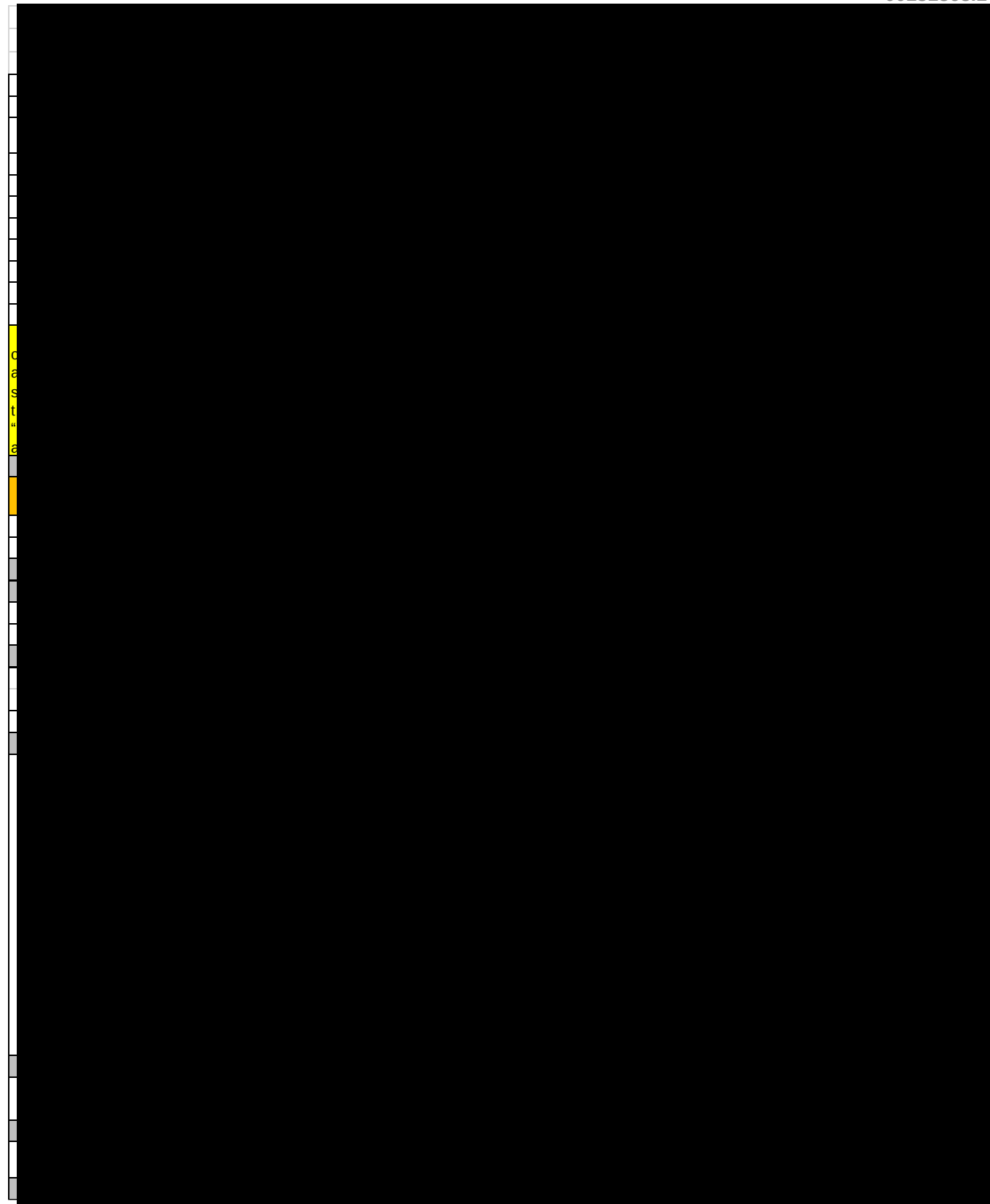
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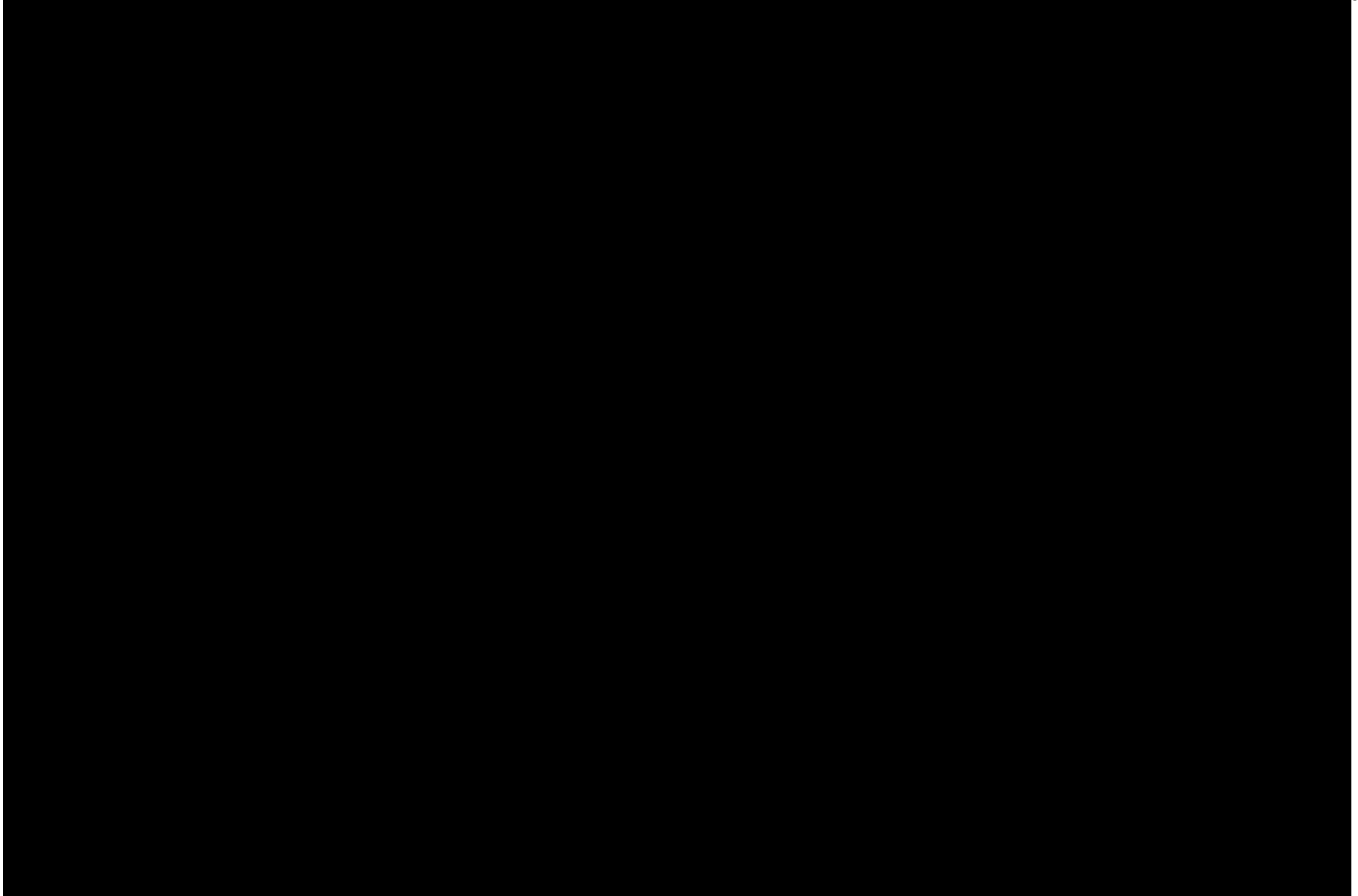
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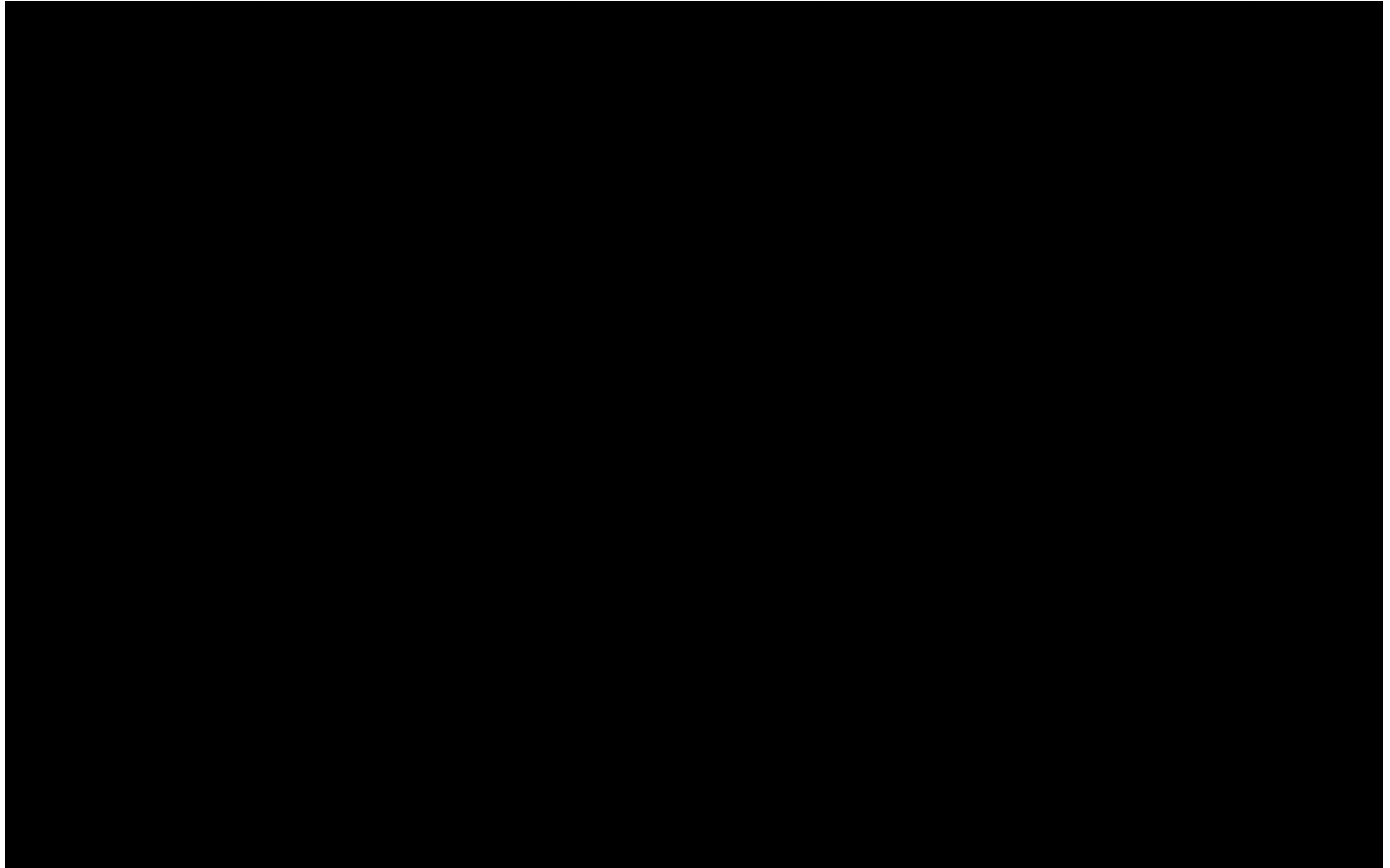
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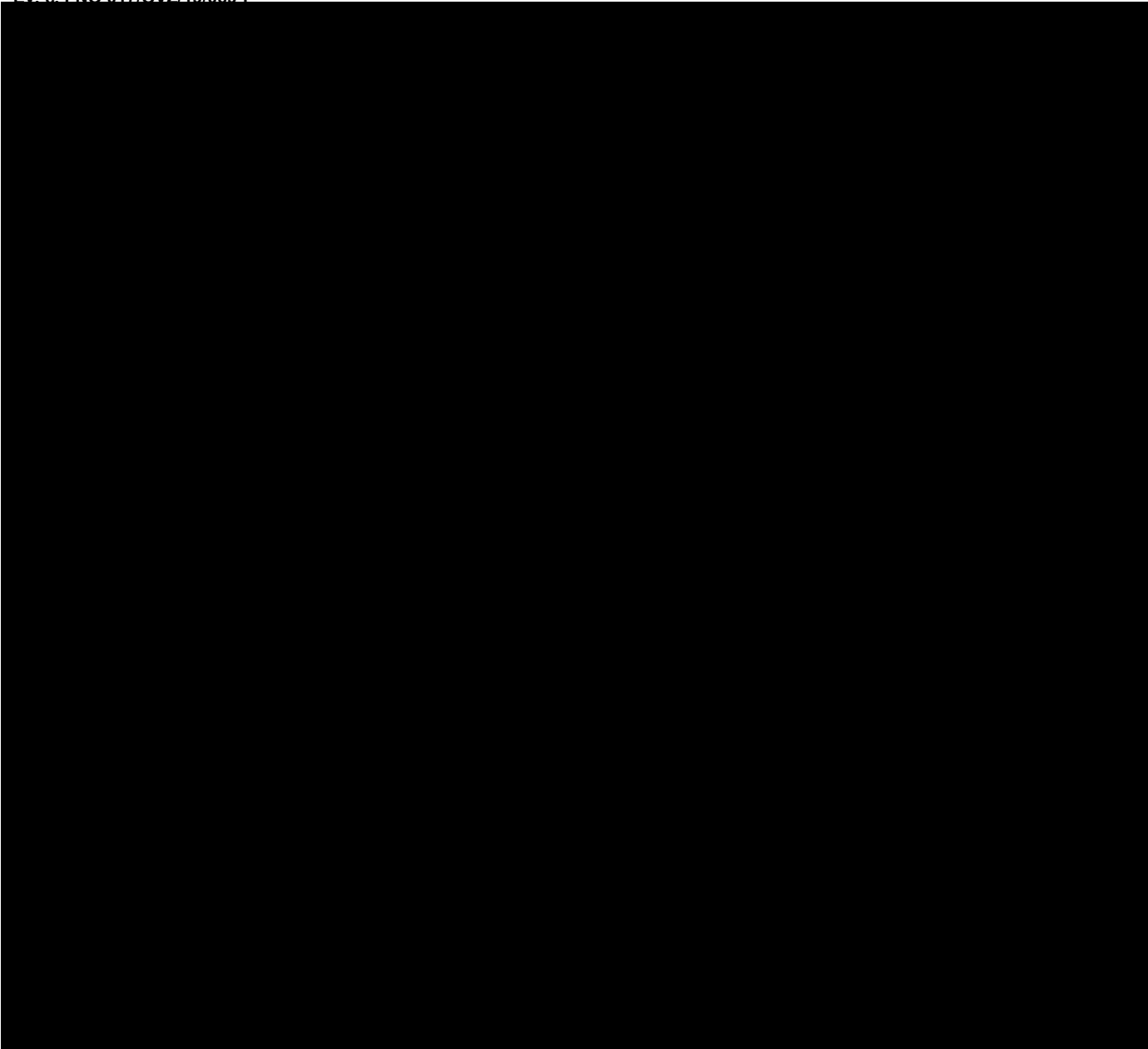
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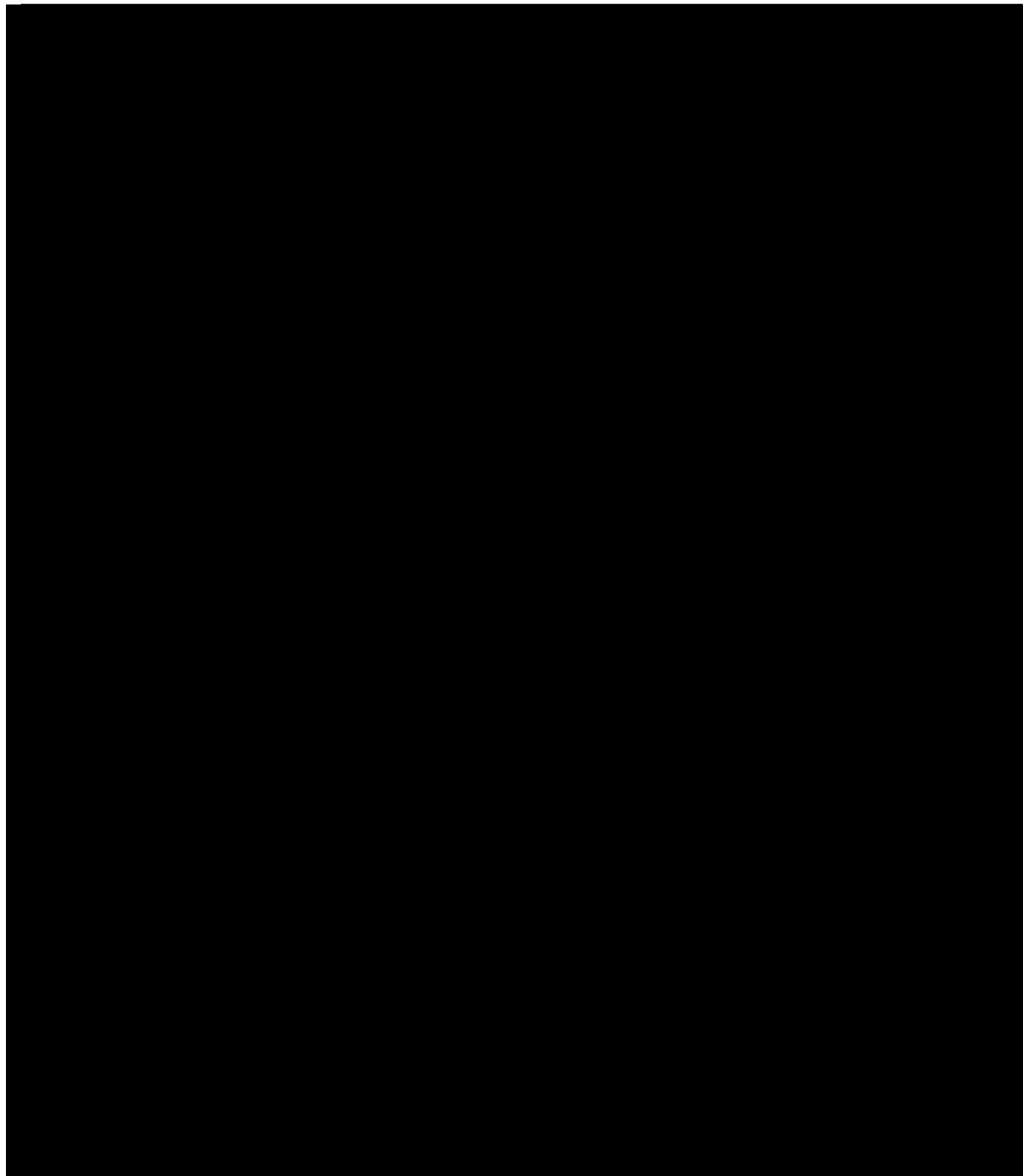
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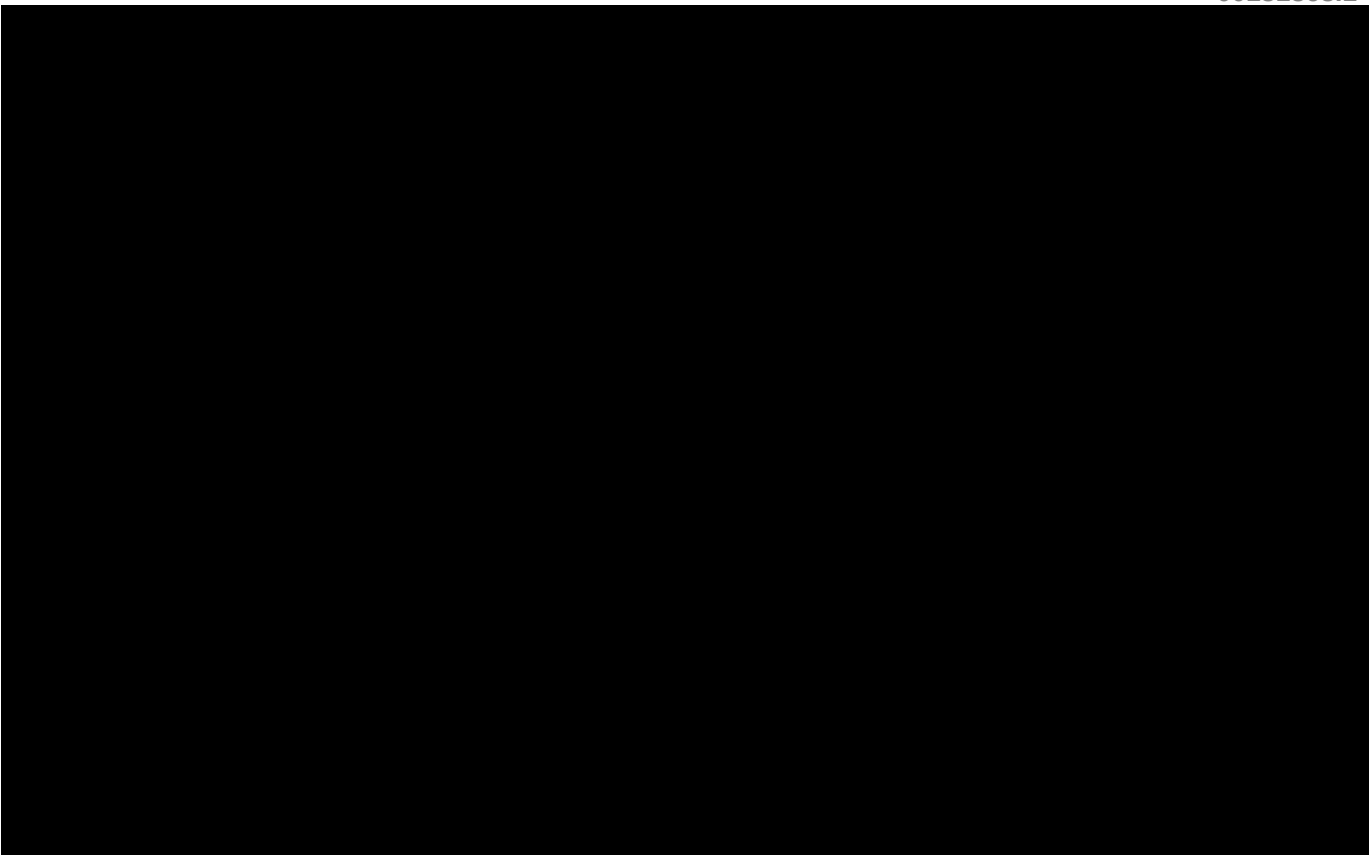
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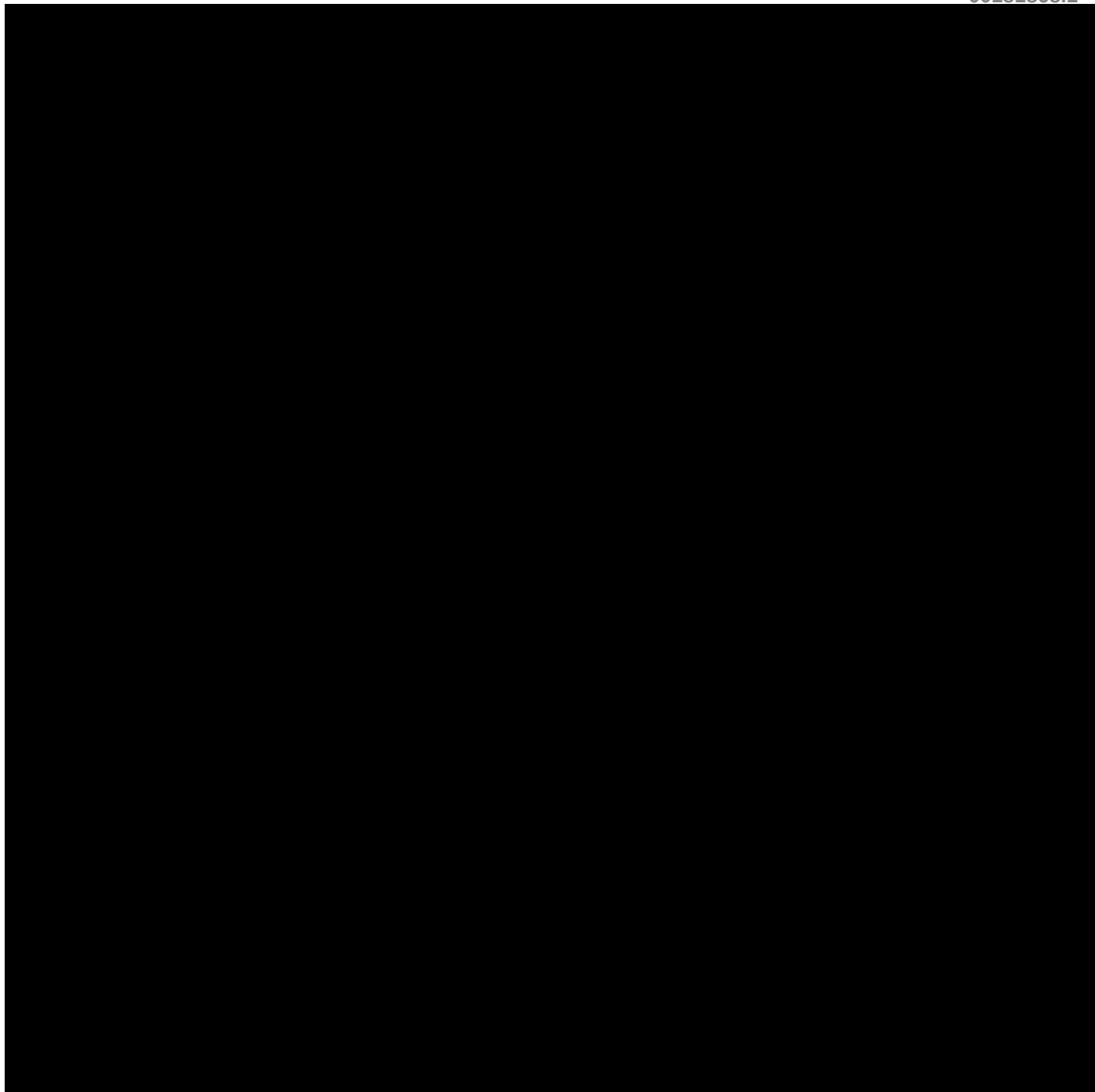
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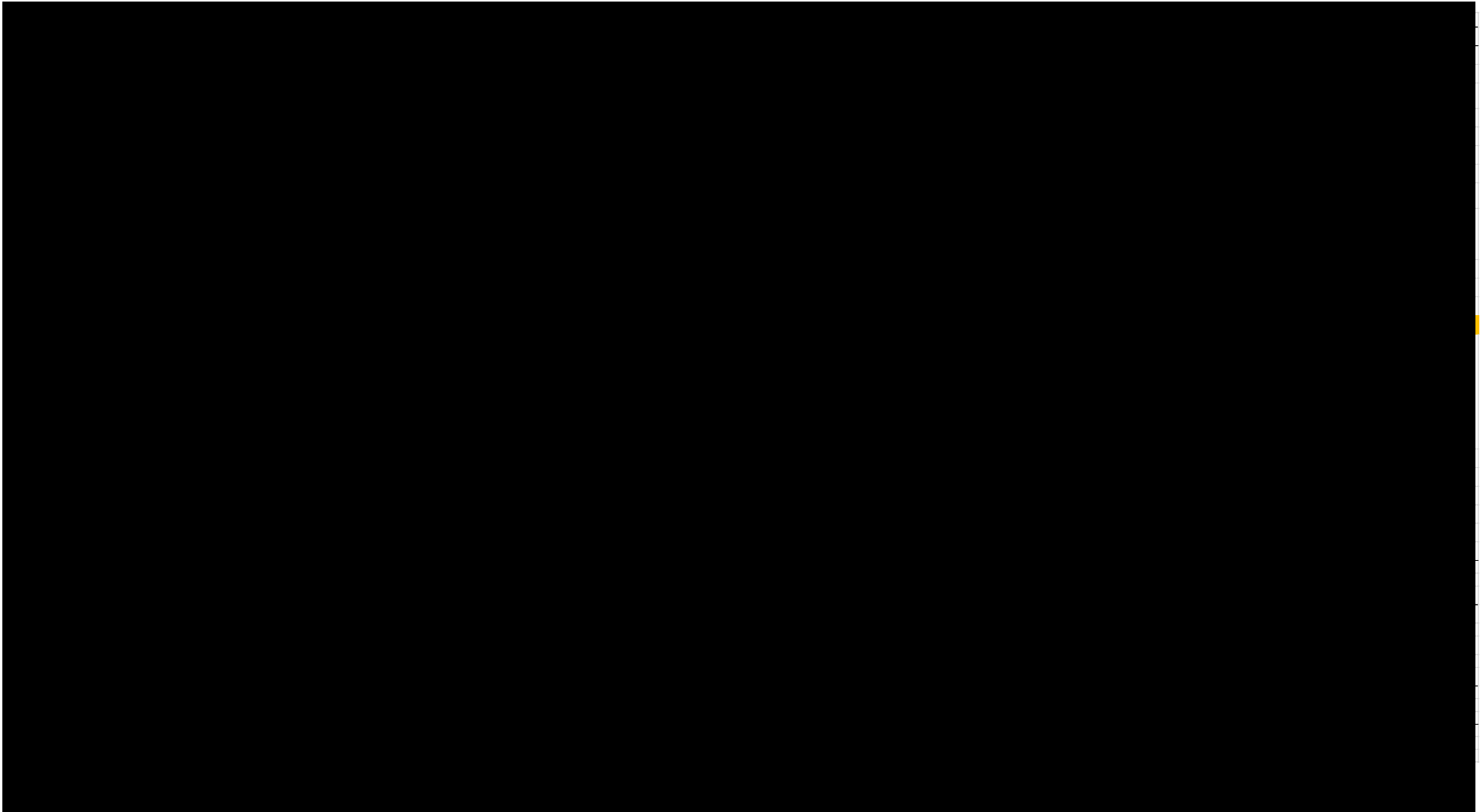
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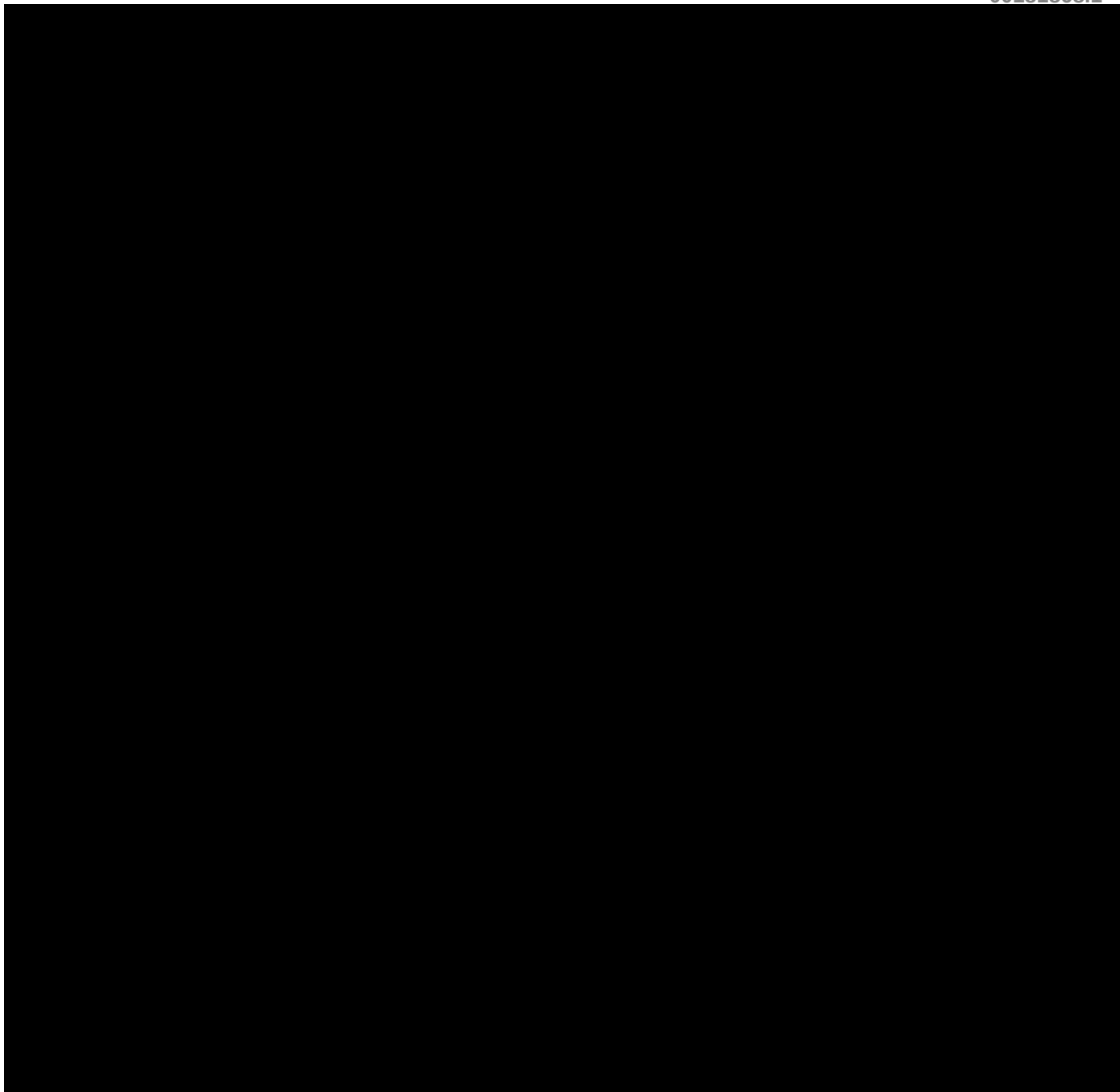
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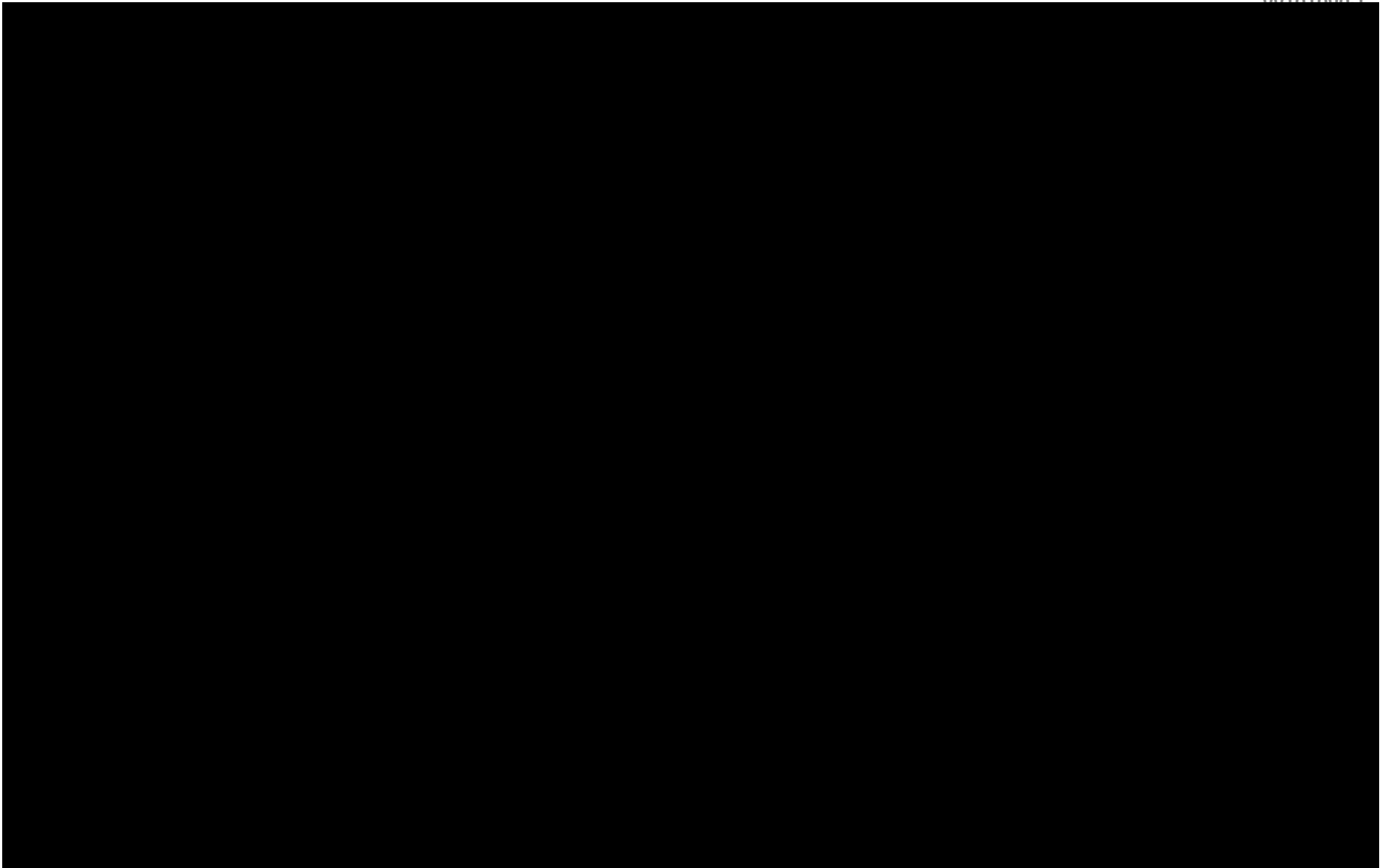
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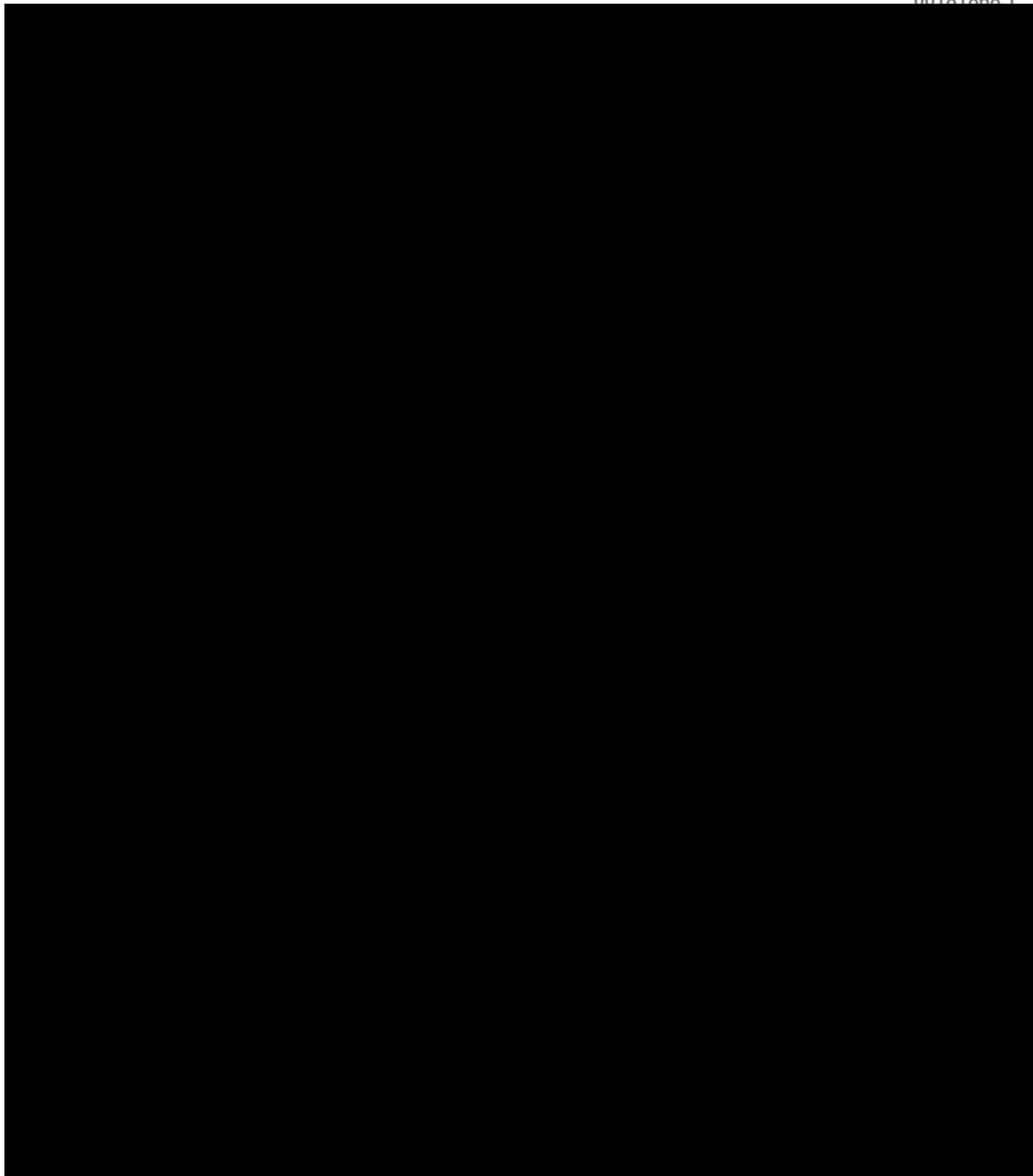
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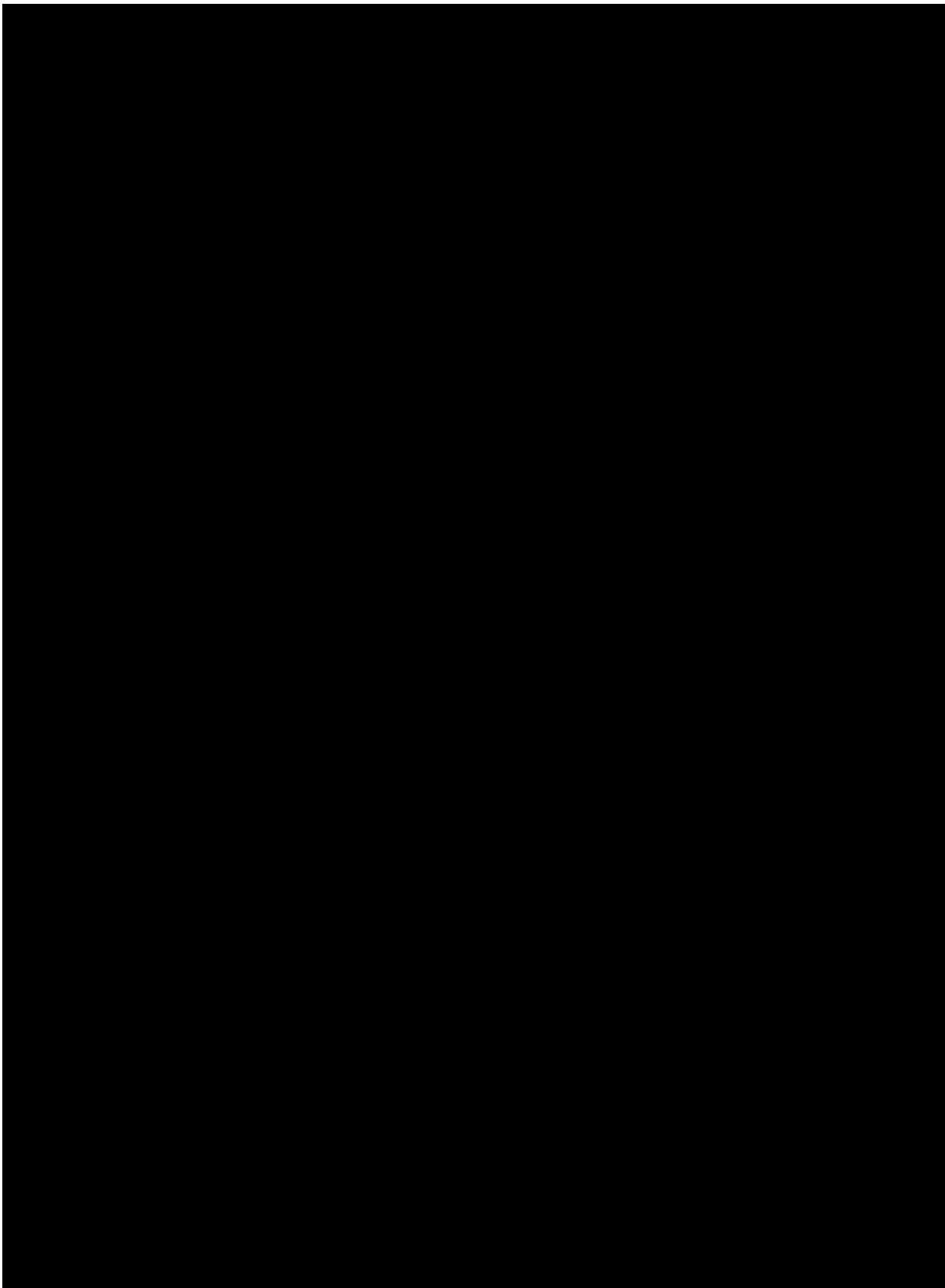
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