



LEVACT[®] (BENDAMUSTYNA) W LECZENIU INDOLENTNYCH CHŁONIAKÓW NIEZIARNICZYCH

ANALIZA EKONOMICZNA

Wersja 1.1

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Autorzy	Wykonywane zadania
[Redacted]	<ul style="list-style-type: none">➤ Koncepcja analizy➤ Przegląd systematyczny badań do oceny jakości życia i innych analiz ekonomicznych➤ Gromadzenie i opracowanie danych wejściowych do modelu➤ Modelowanie➤ Analiza wrażliwości➤ Analiza progowa➤ Identyfikacja i opracowanie ograniczeń analizy➤ Opracowanie wyników➤ Kontrola jakości➤ Wnioski i dyskusja
[Redacted]	<ul style="list-style-type: none">➤ Przegląd systematyczny badań do oceny jakości życia i innych analiz ekonomicznych
[Redacted]	<ul style="list-style-type: none">➤ Przegląd systematyczny badań do oceny jakości życia i innych analiz ekonomicznych

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Konflikt interesów:

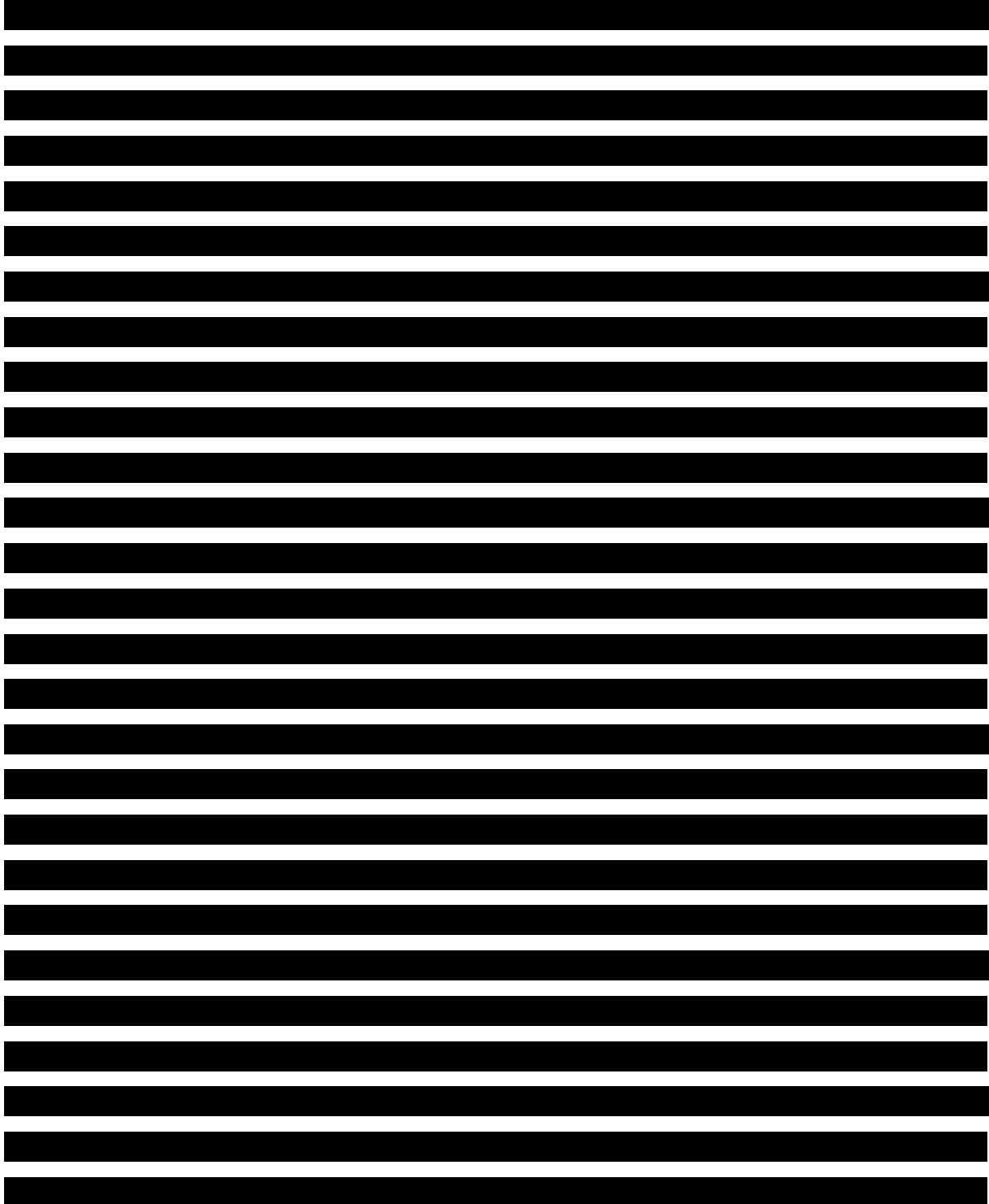
Raport wykonano na zlecenie firmy Mundipharma Polska Sp. z o.o., która finansowała pracę.

Autorzy nie mieli innego rodzaju konfliktu interesów.

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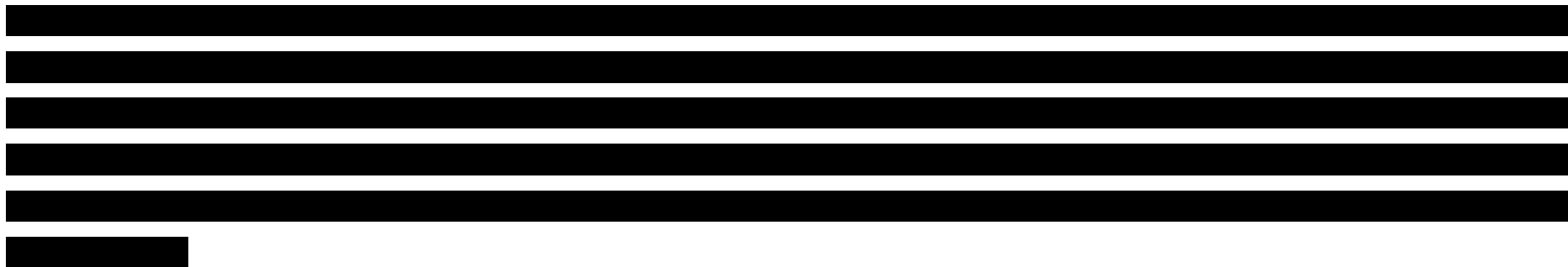
Streszczenie

CEL I ZAKRES ANALIZY

Celem analizy była ocena opłacalności stosowania w Polsce bendamustyny (nazwa handlowa Levact®) w leczeniu chorych z indolentnymi chłoniakami nieziarnicznymi (wcześniej leczonych rytuksymabem) w ramach nowego programu lekowego. Doboru komparatorów oparto na podstawie przeprowadzonych analiz - *Analizy problemu decyzyjnego* oraz *Analizy klinicznej*.

METODYKA

W celu oceny opłacalności stosowania produktu Levact® we wskazanej populacji chorych, zastosowano technikę analityczną kosztów-użyteczności, w której za jednostkę efektu zdrowotnego przyjęto długość życia skorygowaną o jakość życia (QALY, ang. *quality-adjusted life years*).



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Modelowanie efektów zdrowotnych zostało wykonane w oparciu o model stworzony od podstaw na potrzeby tej analizy – uwzględniał on warunki polskiej praktyki klinicznej m.in. w kwestii doboru komparatorów, wysokości i struktury ponoszonych kosztów.

[REDACTED]

[REDACTED]

[REDACTED]

W celu określenia efektów zdrowotnych zastosowania terapii w rozpatrywanej populacji posłużono się wynikami przedstawionymi w badaniach odnalezionych w ramach *Analizy klinicznej* [REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]

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WNIOSKI

[REDACTED]

Na podstawie uzyskanych w analizie wyników określić można, że finansowanie terapii bendamustyną w ramach nowego programu lekowego jest zasadne [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. Cel i zakres analizy ekonomicznej

Analiza została przygotowana w celu oceny opłacalności stosowania w Polsce bendamustyny (nazwa handlowa Levact®) w leczeniu chorych z indolentnymi chłoniakami nieziarnicznymi (uprzednio leczonych rytuksymabem), w ramach nowego programu lekowego.

Doboru komparatorów dokonano w oparciu o *Analizę problemu decyzyjnego* [30] oraz *Analizę kliniczną* [29].

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Wyniki uzyskano w oparciu o wykonany na potrzeby analizy model, uwzględniający warunki polskiej praktyki klinicznej, w szczególności związane z kosztami porównywanych terapii.

2. Strategia analityczna

Analiza ekonomiczna opiera się na wykonanym od podstaw modelu, odpowiadającemu warunkom polskiej praktyki klinicznej m.in. w kwestii doboru komparatorów, wysokości i struktury ponoszonych kosztów. W analizie wykorzystano zarówno wyniki badań odnalezionych w ramach *Analizy klinicznej* [29], jak i wyniki innych badań odszukanych na potrzeby analizy ekonomicznej

3. Perspektywa

Wykonany model pozwala na uzyskanie wyników zarówno w perspektywie płatnika publicznego jak i w perspektywie poszerzonej (obejmującej oprócz płatnika publicznego także pacjenta), gdyż zgodnie z *Rozporządzeniem ws. minimalnych wymagań* analizę wykonano zarówno w perspektywie płatnika publicznego jak i w perspektywie poszerzonej.

4. Horyzont czasowy

Zgodnie w Wytycznymi Agencji Oceny Technologii Medycznych (AOTM) horyzont czasowy analizy ekonomicznej powinien być wystarczająco długi, aby możliwa była ocena różnic między wynikami i kosztami ocenianej technologii medycznej oraz komparatorów [1].

[REDACTED]

5. Dyskontowanie

W ocenie zasadności finansowania danej technologii medycznej należy uwzględnić koszty i efekty kliniczne jakie będzie ona generowała w określonym horyzoncie czasowym. Zgodnie z teorią ekonomii, wartości przyszłe ponoszonych kosztów (i uzyskiwanych efektów zdrowotnych) nie są równe wartościom kosztów (ani uzyskiwanym efektom zdrowotnym) ponoszonych w chwili obecnej. W celu uniknięcia błędów, wartości przyszłe należy wyrazić w wartościach terażniejszych, czemu służy dyskontowanie.

Zgodnie z Wytycznymi AOTM w analizie przyjęto stopę dyskontową na poziomie 5% dla kosztów oraz 3,5% dla wyników zdrowotnych [1].

Ponadto w analizie wrażliwości uwzględniono stopy dyskontowe na poziomie: 5% dla kosztów i wyników zdrowotnych; 0% dla kosztów i wyników zdrowotnych; 0% dla wyników zdrowotnych i 5% dla kosztów.

6. Przegląd systematyczny badań do oceny jakości życia chorych z indolentnymi chłoniakami nieziarnicznymi

Oprócz wyników zdrowotnych z badań klinicznych, w modelu konieczne było również określenie jakości życia chorych w analizowanym wskazaniu. Z tego względu wykonano przegląd systematyczny, mający na celu odnalezienie publikacji przedstawiających rezultaty badań jakości życia chorych z indolentnymi chłoniakami nieziarnicznymi.

6.1. Kryteria włączenia i wykluczenia badań do oceny jakości życia chorych

Celem wykonanego przeglądu było odnalezienie badań spełniających poniżej zdefiniowane kryteria, które zostały ustanowione *a priori* w protokole do przeglądu systematycznego.

Kryteria włączenia badań:

[Redacted text block containing inclusion criteria]

Kryteria wykluczenia badań:

[Redacted text block containing exclusion criteria]

6.2. Strategia wyszukiwania

W celu odnalezienia badań do oceny jakości życia chorych zastosowano strategie wyszukiwania. [Redacted text]

[Redacted text] Strategie te zawierają terminy odnoszące się do wyżej zdefiniowanych kryteriów włączenia badań.

[REDACTED]

Zakładanym wynikiem przeglądu było odnalezienie badań umożliwiających ocenę jakości życia chorych w analizowanym wskazaniu, z uwzględnieniem stanów przyjętych w modelu oraz punktów końcowych, określonych w badaniach, włączonych do *Analizy klinicznej*.

6.3. Selekcja badań

Odnalezione publikacje [REDACTED] zostały poddane selekcji na podstawie tytułów i streszczeń, a następnie pełnych tekstów. Selekcji dokonało niezależnie dwóch analityków [REDACTED]. W przypadku braku zgodności decyzje podejmowane były z udziałem trzeciego analityka [REDACTED] na drodze konsensusu. Selekcję oparto na wcześniej zdefiniowanych kryteriach włączenia i wykluczenia, opisanych w rozdziale 6.1.

Proces selekcji badań do oceny jakości życia zobrazowano na diagramie, [REDACTED]

6.4. Publikacje do oceny jakości życia chorych odnalezione na podstawie przeglądu systematycznego i włączone do analizy

W wyniku przeszukiwania głównych baz informacji medycznej [REDACTED] odnaleziono [REDACTED] publikacji w formie tytułów i abstraktów.

[REDACTED]

[REDACTED]

[REDACTED]

Po przeprowadzeniu selekcji abstraktów włączono [REDACTED] do analizy pełnych tekstów. Po przeprowadzeniu selekcji na podstawie pełnych tekstów ostatecznie do analizy włączono [REDACTED] przydatnych do oceny jakości życia chorych z indolentnymi chłoniakami nieziarnicznymi.

Publikacje włączone do analizy na podstawie oceny pełnych tekstów:

[REDACTED]

[REDACTED]

[REDACTED]

6.5. Metodyka publikacji włączonych do oceny jakości życia chorych

[REDACTED]

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6.6. Źródła danych o jakości życia z publikacji włączonych do oceny jakości życia

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7. Ocena wyników zdrowotnych

7.1. Jakość życia

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7.2. Skuteczność kliniczna i profil bezpieczeństwa

W *Analizie klinicznej* scharakteryzowane zostały punkty końcowe brane pod uwagę w badaniach oceniających efekty i bezpieczeństwo terapii bendamustyną oraz alternatywnych terapii. W poniższych rozdziałach przedstawiono efekty terapii mające bezpośredni wpływ na efekty zdrowotne i koszty terapii.

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8. Przegląd systematyczny innych analiz ekonomicznych wykonanych w Polsce lub za granicą

8.1. Kryteria włączenia i wykluczenia innych analiz ekonomicznych

Celem przeglądu innych analiz ekonomicznych wykonanych w Polsce lub za granicą było odszukanie publikacji spełniających poniżej przedstawione kryteria, które zostały ustanowione *a priori* w protokole do przeglądu systematycznego.

Kryteria włączenia badań:

[Redacted text]

Kryteria wykluczenia badań:

[Redacted text]

[REDACTED]

[REDACTED]

[REDACTED]

8.2. Strategia wyszukiwania

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Zakładanym wynikiem przeglądu było odnalezienie publikacji prezentujących wyniki innych analiz ekonomicznych, wykonanych w kraju lub za granicą, dotyczących wskazanego problemu zdrowotnego oraz opłacalności stosowania ocenianej interwencji względem zdefiniowanego komparatora.

8.3. Selekcja badań

[Redacted text block containing multiple lines of blacked-out content]

9. Technika analityczna

Ponieważ zależna od zdrowia jakość życia jest w omawianym problemie zdrowotnym „jednym z istotnych wyników analizowanych technologii medycznych”, zdecydowano o przeprowadzeniu analizy ekonomicznej **techniką kosztów-użyteczności** (CUA, ang. *cost-utility analysis*) [1]. Jako efekt zdrowotny w analizie kosztów użyteczności przyjęto punkt końcowy wyrażany przez skorygowaną o jakość życia, długość życia chorego w okresie przyjętym za długość linii leczenia – okresie, dla którego można na podstawie badań określić skuteczność i bezpieczeństwo rozpatrywanych terapii (przyjęty horyzont czasowy).

Zgodnie z Wytycznymi Agencji Oceny Technologii Medycznych (AOTM) [1], przeprowadzono także analizę **kosztów i konsekwencji** (CCA, ang. *cost-consequences analysis*).

10. Analiza kosztów

W analizie uwzględniono koszty odpowiadające zużyciu zasobów w praktyce klinicznej w Polsce. Wszystkie różnice w kosztach ujawniają się w przyjętym dla analizy horyzoncie czasowym [REDACTED]

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11. Modelowanie

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Model został opracowany tak aby odpowiadał polskiej praktyce klinicznej – w szczególności aby oddawał wielkość kosztów związanych z zastosowaniem każdego ze schematów (bendamustyny bądź komparatorów) związanych z uzyskaniem efektów zdrowotnych modelowanych na podstawie dostępnych badań.

Model wykonano w programie MS Excel 2007. Modelowaniu podlegały efekty zdrowotne i koszty związane z terapią chorych z indolentnymi chłoniakami nieziarniczymi.

Wytyczne AOTM wskazują, że struktura modelu wykorzystywanego w analizie ekonomicznej powinna być prosta, ale jednocześnie model musi odpowiadać problemowi zdrowotnemu i musi być zgodny z ogólnie akceptowaną wiedzą na temat przebiegu modelowanej choroby [1].

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14. Jednokierunkowa analiza wrażliwości

Jednokierunkową analizę wrażliwości przeprowadzono dla parametrów, które w największym stopniu obarczone są niepewnością, a mogą mieć duży wpływ na końcowe wyniki. Dla parametrów tych przeprowadzono analizę wartości skrajnych (ang. *extreme value analysis*), która badała wpływ przyjęcia przez te parametry wartości skrajnych na wyniki końcowe – określając przedział ich wartości.

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Analizę wrażliwości wykonano dla perspektywy poszerzonej i perspektywy płatnika publicznego [REDACTED]

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Zgodnie z *Wytycznymi AOTM* analizie wrażliwości poddano obraną wysokość dyskontowania dla kosztów i efektów zdrowotnych. W analizie wrażliwości, w pierwszym wariantcie rozpatrzono stopę dyskontowania po 5% dla kosztów i efektów zdrowotnych; w drugim - stopę dyskontowania po 0% dla obu wielkości; w trzecim - przyjęto stopę dyskonta 0% dla efektów zdrowotnych i 5% dla kosztów.

Pełna lista parametrów użytych w analizie znajduje się w poniższej tabeli, wraz z zakresem zmienności – opisanym dalej.

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15. Wielokierunkowa probabilistyczna analiza wrażliwości

W celu określenia niepewności wyników przeprowadzono wielokierunkową probabilistyczną analizę wrażliwości. [REDACTED]

W przypadku wszystkich parametrów dysponowano prawdopodobną oraz minimalną i maksymalną wartością parametru. W tej sytuacji, w przypadku parametrów, dla których nie możliwe było określenia odchylenia standardowego zdecydowano się w modelować rozkład parametrów za pomocą rozkładu trójkątnego, szczególnie przydatnego, gdy nie można oszacować odchylenia standardowego parametrów. Jeśli możliwe było wykorzystanie odchylenia standardowego to stosowano rozkład normalny.

15.1. Parametry uwzględnione w wielokierunkowej probabilistycznej analizie wrażliwości

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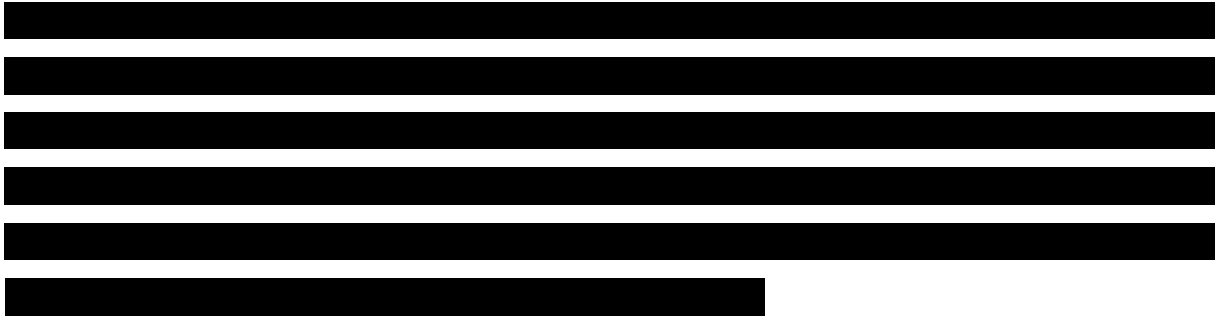
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17. Progowa analiza wrażliwości



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18.1. Sposób prezentacji efektu zdrowotnego

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18.2. Prezentacja zdarzeń w czasie

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18.3. Zakres danych wykorzystywanych do przedstawienia wyników

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19. Ograniczenia

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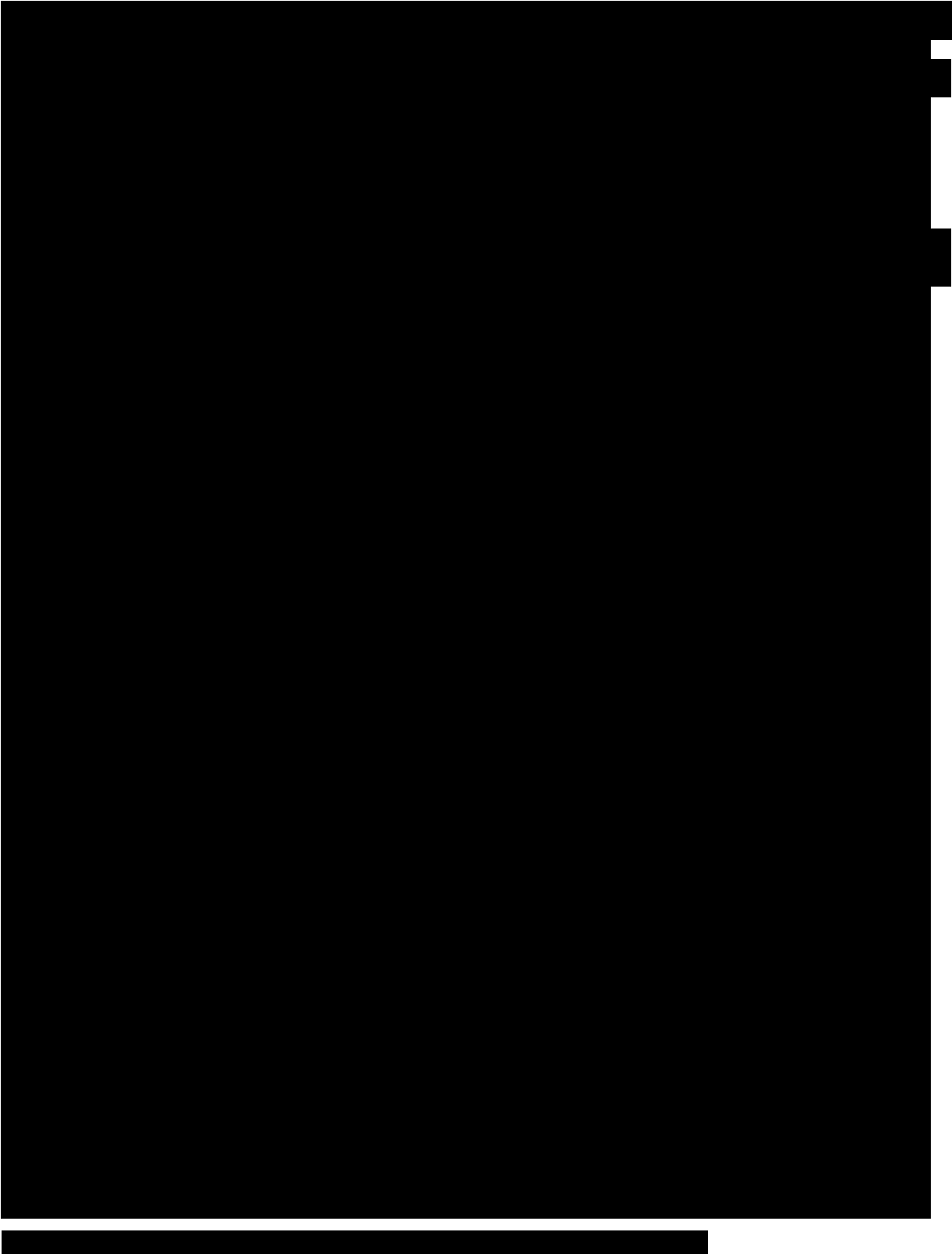
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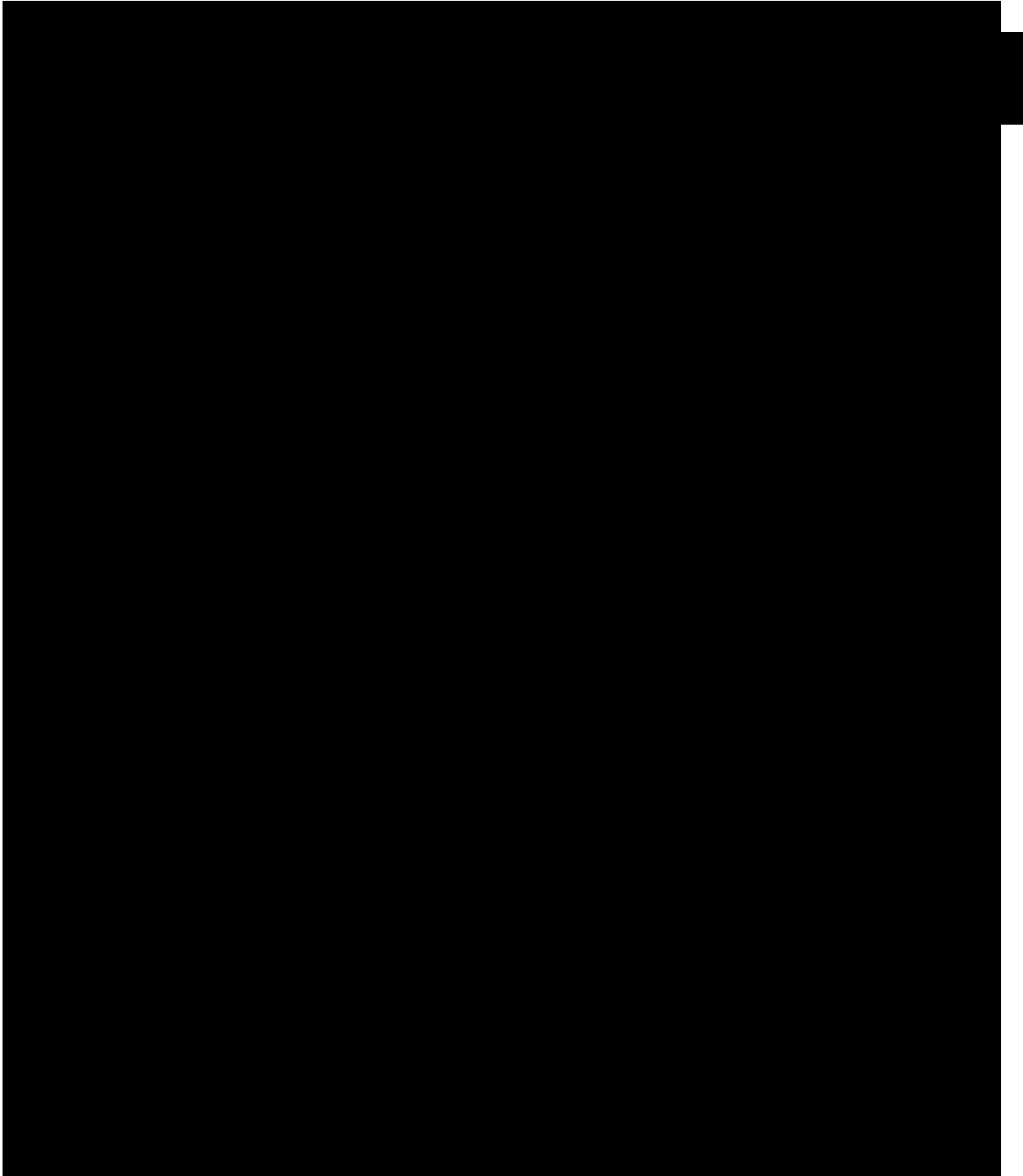
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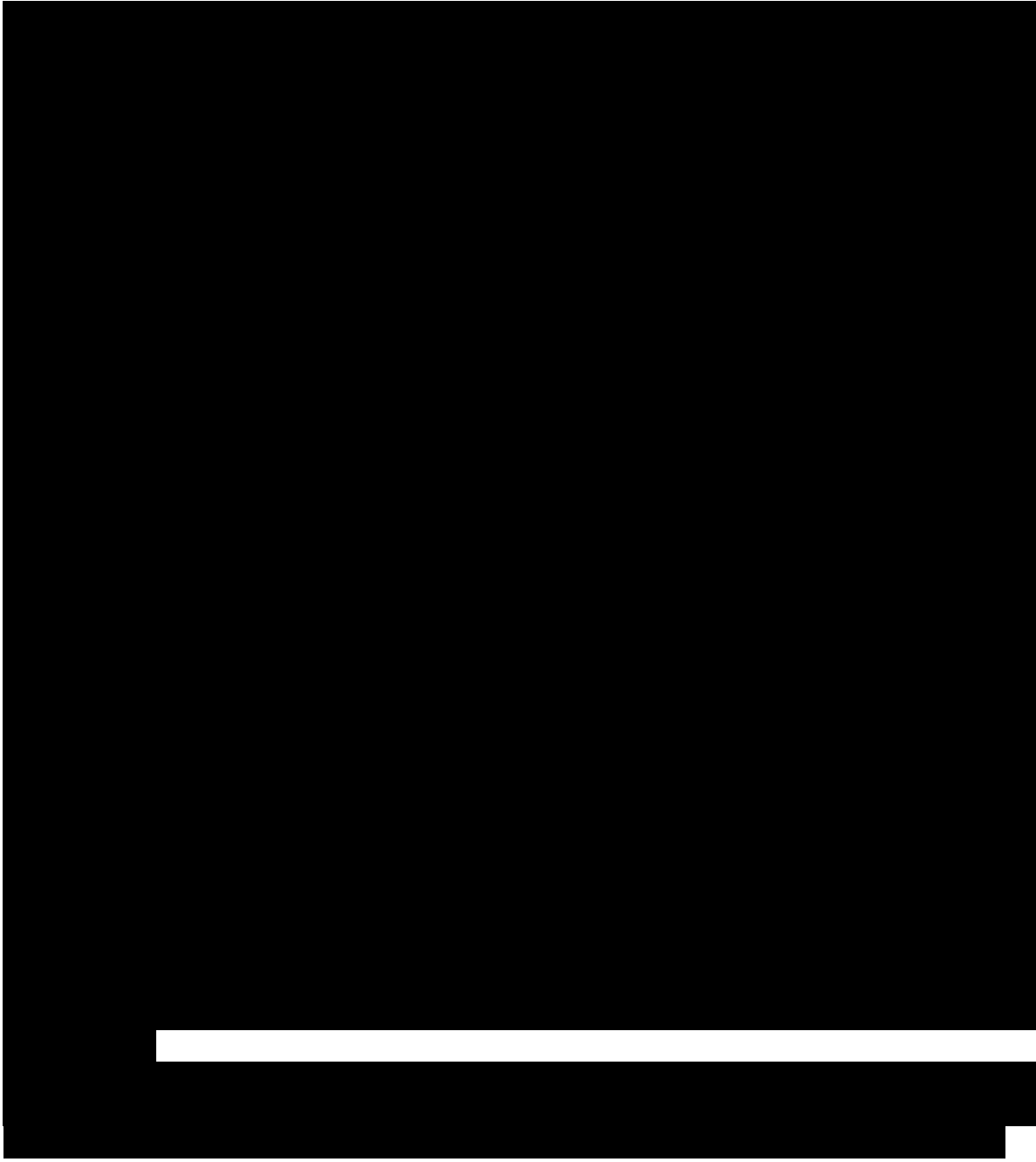
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24. Spis rysunków



25. Bibliografia

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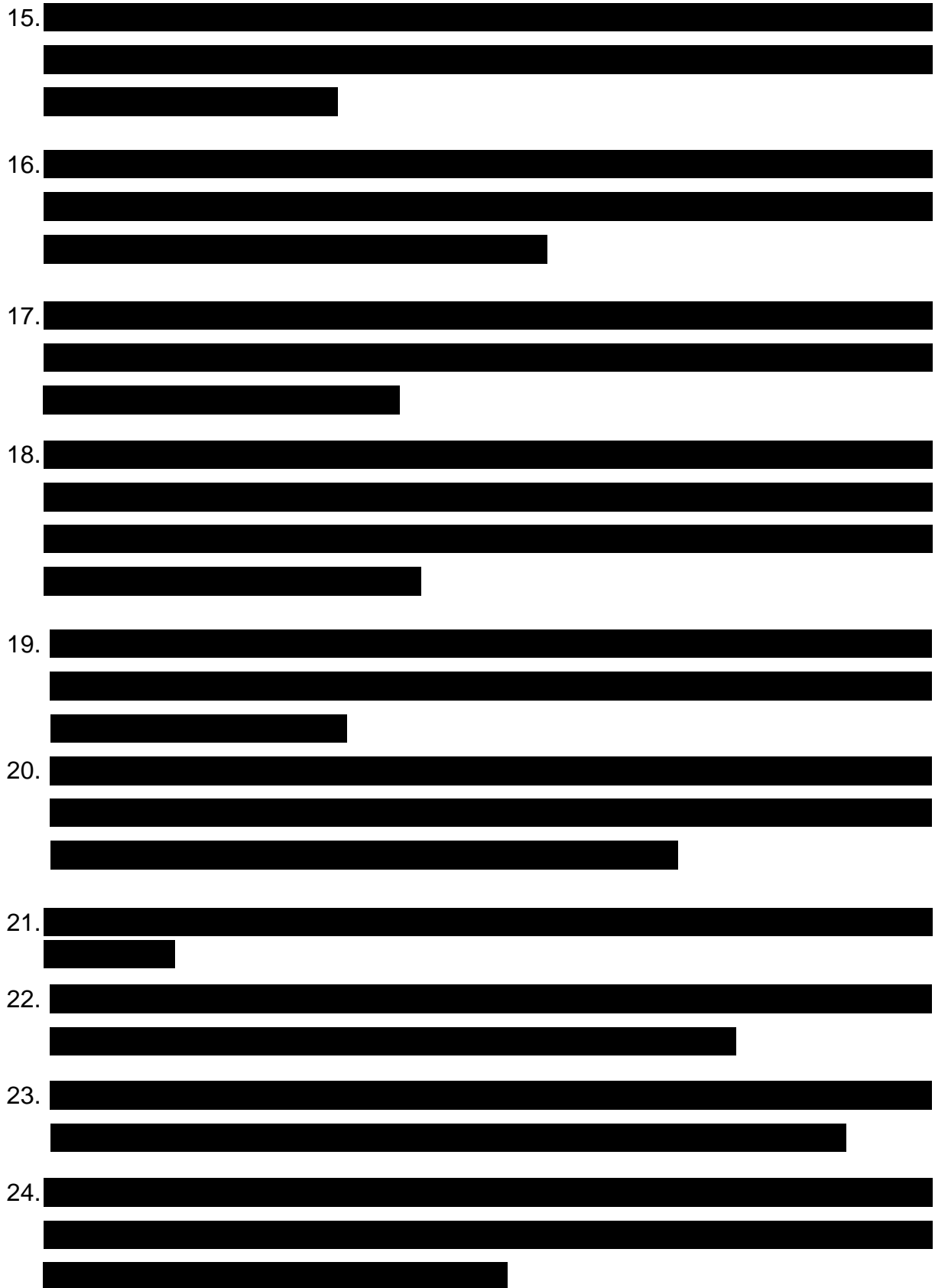
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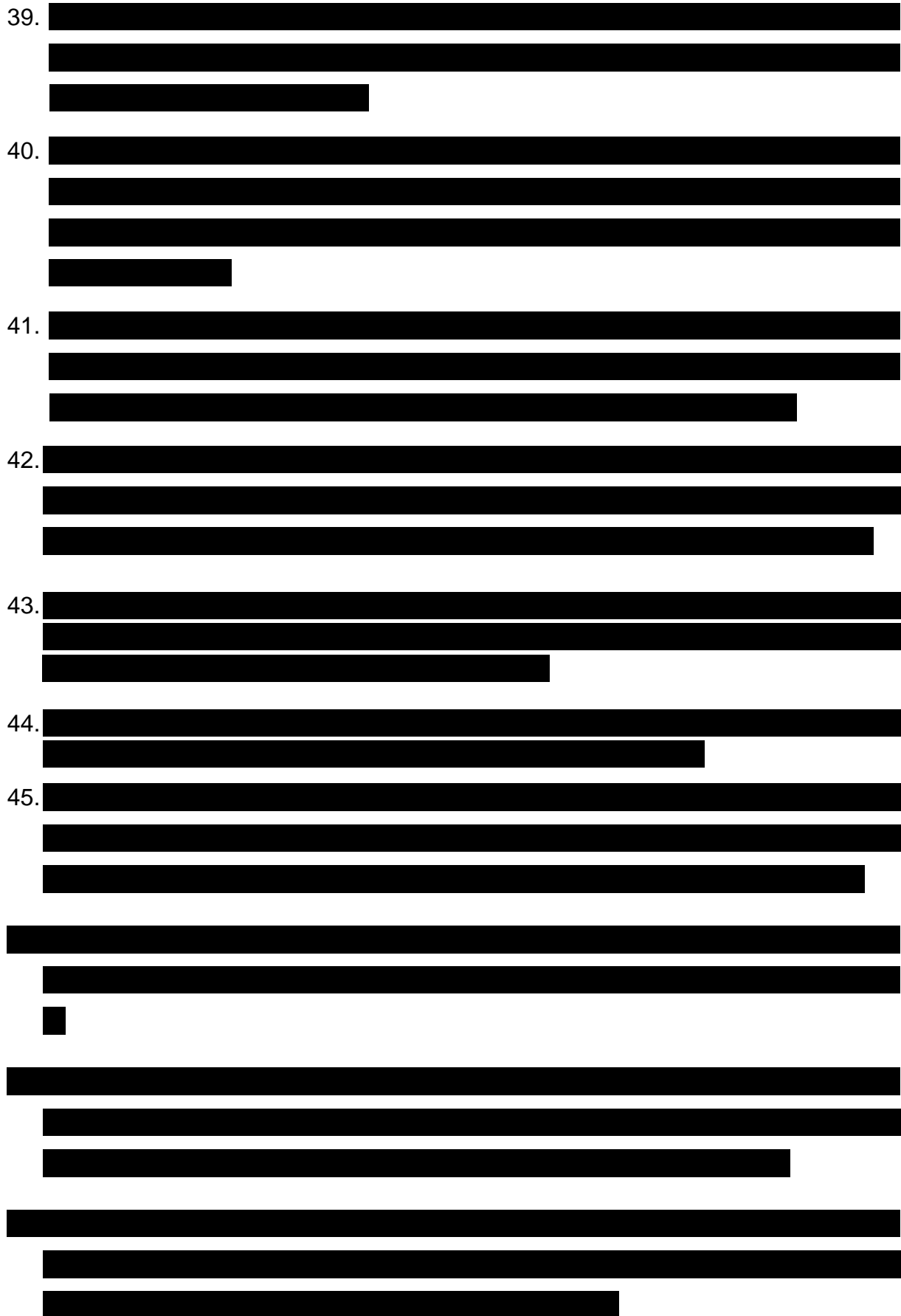
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