

**BEWACYZUMAB W LECZENIU  
PIERWSZEGO RZUTU CHORYCH NA  
NABŁONKOWEGO RAKA JAJNIKA, RAKA  
JAJOWODU I PIERWOTNEGO RAKA  
OTRZEWNEJ W STADIUM  
ZAAWANSOWANIA III LUB IV**

**ANALIZA KLINICZNA**

Wersja 1.0

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Warszawa, 31 maja 2012

**Autorzy**

**Wykonywane zadania**

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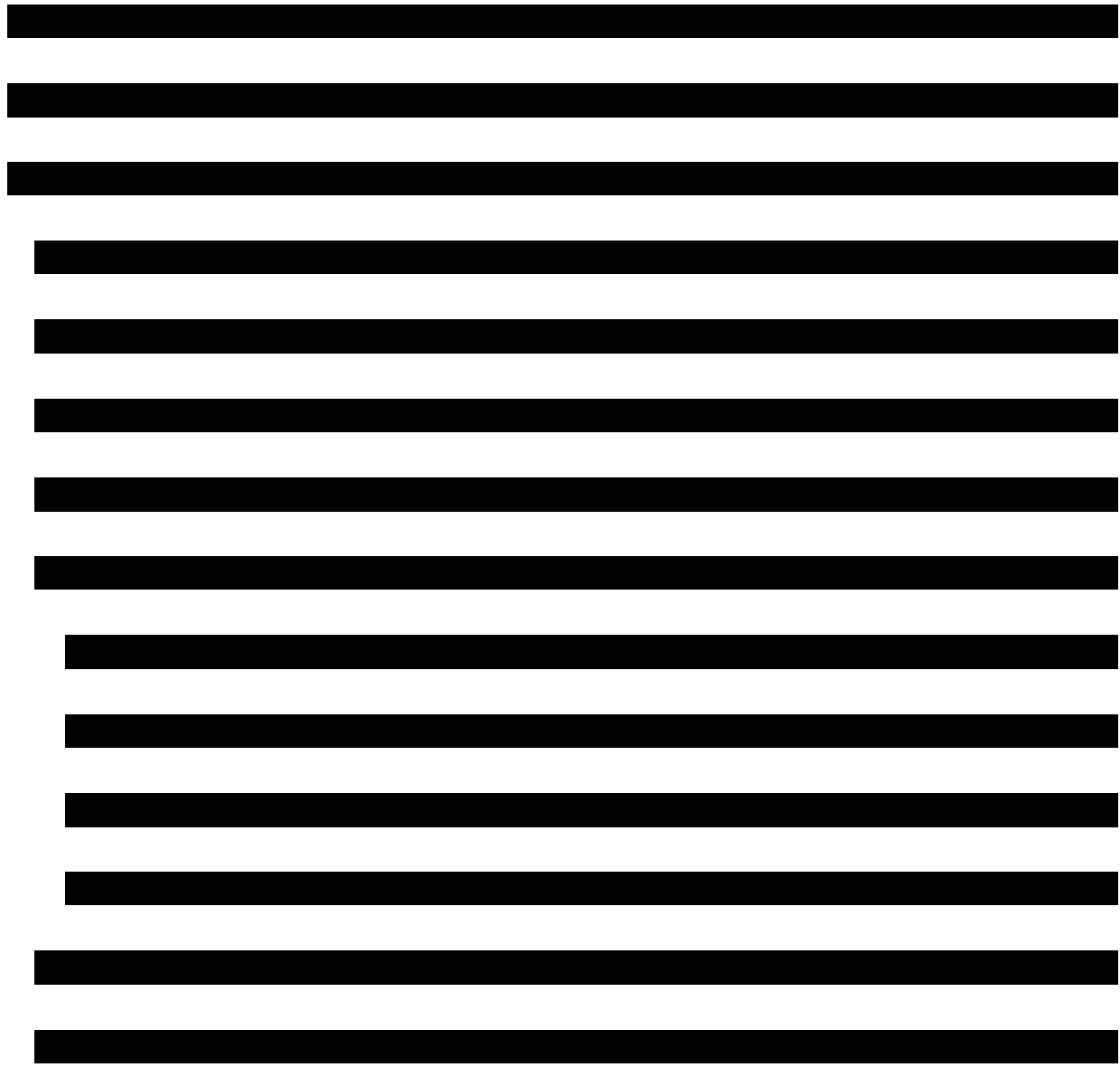
## Spis treści

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## Streszczenie

### CEL

Celem raportu jest porównawcza analiza skuteczności i bezpieczeństwa bewacyzumabu (BEW) w dawce 15 mg/kg mc. (miligramów na kilogram masy ciała) w schemacie z paklitakselem i karboplatiną (CHEM) [REDACTED]

[REDACTED], stosowanych w leczeniu pierwszego rzutu chorych na nabłonkowego raka jajnika, raka jajowodu oraz pierwotnego raka otrzewnej w stadium zaawansowania III lub IV wg FIGO (fr. *Fédération Internationale de Gynécologie et d'Obstétrique* - Światowa Organizacja Ginekologii i Położnictwa).

Wykonana zostanie również porównawcza analiza efektywności klinicznej bewacyzumabu (BEW) w dawce 7,5 mg/kg mc. w schemacie z paklitakselem i karboplatiną (CHEM) [REDACTED]

[REDACTED] stosowanych w leczeniu pierwszego rzutu nabłonkowego raka jajnika, raka jajowodu oraz pierwotnego raka otrzewnej w grupie chorych wysokiego ryzyka (tj. w stadium zaawansowania III wg FIGO po suboptymalnej cytoredukcji oraz w stadium zaawansowania IV wg FIGO po zabiegu cytoredukcyjnym).

### METODYKA

Przegląd systematyczny został wykonany zgodnie z Wytycznymi Agencji Oceny Technologii Medycznych (AOTM), stanowiącymi załącznik do Zarządzenia nr 1/2010 Prezesa Agencji Oceny Technologii Medycznych z dnia 4 stycznia 2010 r. w sprawie wytycznych oceny świadczeń opieki zdrowotnej oraz zasadami przedstawionymi w „*Cochrane Handbook for Systematic Reviews of Interventions*”, wersja 5.1.0. Przeprowadzono wyszukiwanie badań pierwotnych i wtórnych w trzech głównych bazach medycznych: Medline, Embase oraz Cochrane Library, a także dodatkowych bazach, zalecanych przez AOTM. Selekcję badań przeprowadzono na podstawie zdefiniowanych kryteriów. Do analizy klinicznej włączano badania spełniające kryteria włączenia zdefiniowane zgodnie ze schematem PICOS (populacja, interwencja, komparatory, punkty końcowe, metodyka).

## WYNIKI

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Z wyżej opisanych wniosków wynika, że zasadnym jest stosowanie bewacyzumabu, szczególnie w dawce 7,5 mg/kg mc. w grupie chorych wysokiego ryzyka (tj. FIGO III po suboptymalnej cytoredukcji oraz IV po zabiegu cytoredukcyjnym), w terapii skojarzonej z chemioterapią z następowym leczeniem podtrzymującym bewacyzumabem w monoterapii w praktyce klinicznej i objęcie go finansowaniem w ramach *Programu lekowego leczenia nabłonkowego raka jajnika, raka jajowodu oraz pierwotnego raka otrzewnej.*

## 1. Cel analizy

Celem raportu jest porównawcza analiza skuteczności i bezpieczeństwa bewacyzumabu (BEW) w dawce 15 mg/kg mc. (miligramów na kilogram masy ciała) w schemacie z paklitakselem i karboplatiną (CHEM) [REDACTED]

[REDACTED] stosowanych w leczeniu pierwszego rzutu chorych na nabłonkowego raka jajnika, raka jajowodu oraz pierwotnego raka otrzewnej w stadium zaawansowania III lub IV wg FIGO (fr. *Fédération Internationale de Gynécologie et d'Obstétrique* - Światowa Organizacja Ginekologii i Położnictwa).

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## 2. Metodyka

Podstawą przeprowadzenia analizy klinicznej jest przegląd systematyczny. Przegląd został wykonany zgodnie z Wytycznymi Agencji Oceny Technologii Medycznych (AOTM), stanowiącymi załącznik do Zarządzenia nr 1/2010 Prezesa Agencji Oceny Technologii Medycznych z dnia 4 stycznia 2010 r. w sprawie wytycznych oceny świadczeń opieki zdrowotnej [1] oraz zasadami przedstawionymi w „*Cochrane Handbook for Systematic Reviews of Interventions*”, wersja 5.1.0. [5]. Problem zdrowotny został opisany w oddzielnym dokumencie stanowiącym *Analizę problemu decyzyjnego* [3], w którym określono aktualną praktykę kliniczną leczenia chorych na nabłonkowego raka jajnika, raka jajowodu, pierwotnego raka otrzewnej, wybrano potencjalne komparatory oraz scharakteryzowano populację docelową.



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<sup>1</sup> Populację docelową stanowią wyłącznie kobiety w obu analizowanych dawkach BEW;

<sup>2</sup> W *Charakterystyce Produktu Leczniczego Avastin*<sup>®</sup> [7] populację docelową stanowią chorzy z nabłonkowym rakiem jajnika, jajowodu i pierwotnym rakiem otrzewnej w stadiach zaawansowania choroby od IIIB do IV wg FIGO, jednak badanie rejestracyjne, na podstawie którego zdefiniowano tę populację obejmowało chorych w stadiach III i IV (a nie tylko IIIB do IV), dlatego zdecydowano o przyjęciu szerszego kryterium włączenia;

<sup>3</sup> W *Charakterystyce Produktu Leczniczego Avastin*<sup>®</sup> [7] dawka ta została uwzględniona w opisie skuteczności klinicznej bewacyzumabu w leczeniu rak jajnika, rak jajowodu i pierwotnego raka otrzewnej, przedstawiono wyniki badania *ICON7*. Ponadto, z informacji od Zamawiającego oraz odnalezionych dokumentów [9, 10] wynika, że BEW w dawce 7,5 mg/kg mc. jest zarejestrowany w Szwajcarii oraz może być również stosowany w Wielkiej Brytanii, gdzie będzie finansowany ze środków *Cancer Drugs Fund*, w ramach regionalnych „oddziałów” NHS (ang. *National Health Service* – brytyjska Narodowa Służba Zdrowia)



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<sup>4</sup> przeglądy spełniające kryteria Cook'a [2]. Konieczne spełnienie co najmniej 4 spośród 5 kryteriów: sprecyzowane pytanie badawcze, przedstawienie zastosowanej strategii wyszukiwania, predefiniowane kryteria włączenia i wykluczania dla badań klinicznych, krytyczna ocena wiarygodności badań klinicznych włączonych do analizy, ilościowa i/lub jakościowa synteza wyników badań;

<sup>5</sup> Nie włączano do analizy badań jednoramiennych dla komparatora

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## 2.5. Ocena jakości badań

Badania eksperymentalne z grupą kontrolną oceniono w skali Jadad. Badania jednoramienne oceniano zarówno w skali NOS (ang. *The Newcastle-Ottawa Scale*), jak i NICE (ang. *The National Institute for Health and Clinical Excellence*). W załączniku 19.6 przedstawiono wzory skal (Tabela 61, Tabela 62, Tabela 63).

Badania eksperymentalne z grupą kontrolną zostaną również ocenione według szczegółowej skali stworzonej przez analityków wykonujących raport. Wzór skali został przedstawiony w załączniku 19.6 (Tabela 66).

Dodatkowo, wpływ jakości badań na wyniki poszczególnych punktów końcowych oceniono w skali GRADE [4]. Wzór skali został przedstawiony w załączniku 19.6 (Tabela 64).

## 2.6. Analiza statystyczna

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<sup>6</sup> Interpretacyjnie parametr HR jest zbliżony do parametru ryzyka względnego. Hazard względny stosuje się przede wszystkim do danych uciętych, tj. takich, dla których nie posiada się wszystkich obserwacji (np. wyznaczenie szansy wystąpienia progresji choroby podczas, gdy w momencie zakończenia badania progresja choroby nie wystąpiła u wszystkich pacjentów).

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### 3. Badania włączone na podstawie przeglądu systematycznego

W wyniku przeszukiwania głównych baz informacji medycznej (Medline, Embase, Cochrane Library) odnaleziono 1 652 publikacji w formie tytułów i abstraktów.

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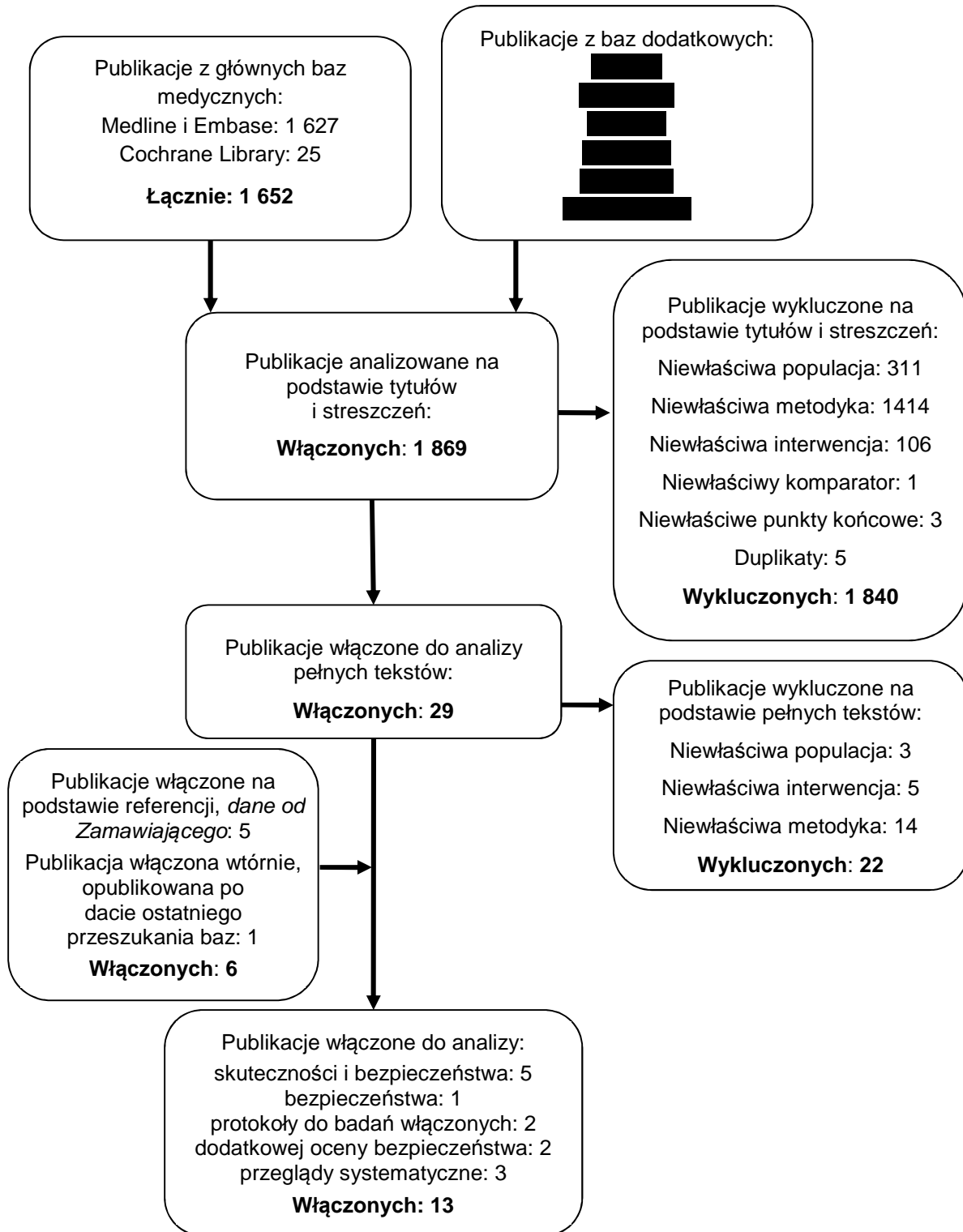
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<sup>7</sup> W badaniu przedstawiono również wyniki w podziale na podgrupy ze względu na stopień zaawansowania choroby, dlatego włączanie w ramach badania również chorych w niskich stadiach zaawansowania choroby nie stanowi podstawy do wykluczenia badania z niniejszej analizy.

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<sup>8</sup> po 6 cyklu zaprzestawano stosowania chemioterapii i podawano w ramach leczenia podtrzymującego jedynie BEW lub PLC. Wyniki dotyczące działań niepożądanych występujących w czasie 48 tygodni terapii podtrzymującej przedstawiono dla porównania BEW vs PLC

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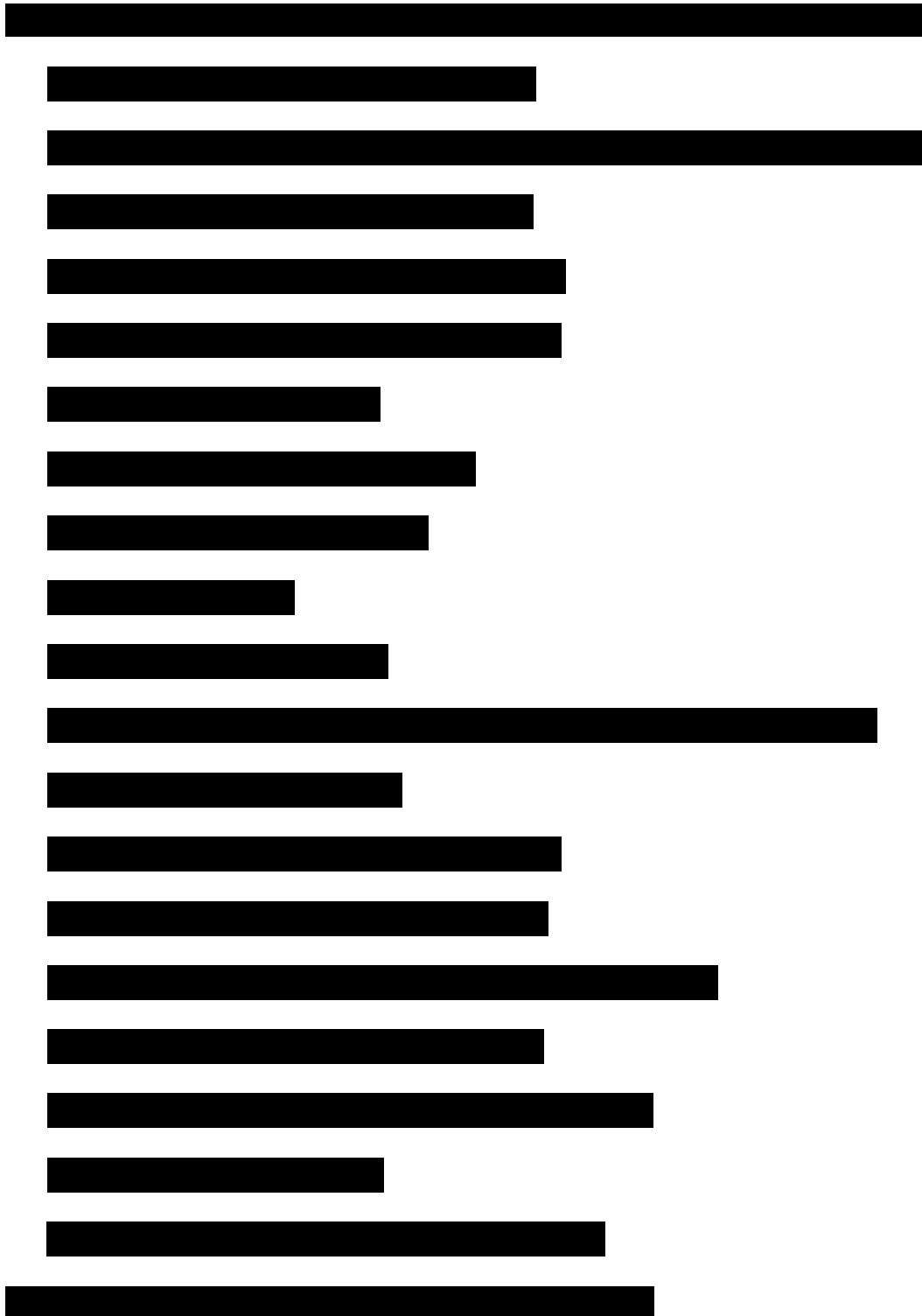
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## 17. Podsumowanie i wnioski końcowe

Analiza efektywności klinicznej bewacyzumabu w dawce 15 mg/kg mc. i 7,5 mg/kg mc. w schemacie z chemioterapią zawierającą karboplatynę i paklitaksel [REDACTED]

Porównanie [REDACTED] BEW w dawce 15 mg/kg mc. + CHEM [REDACTED]

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Porównanie [REDACTED] BEW w dawce 7,5 mg/kg mc. + CHEM [REDACTED]

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## 19.2. Zakończone (nieopublikowane), trwające lub planowane badania kliniczne

Tabela 57.

Zakończone (nieopublikowane), trwające lub planowane badania kliniczne dla bewacyzumabu w schemacie z paklitakselem i karboplatiną w populacji docelowej

Tytuł	Numer identyfikacyjny	Status	Sponsor	Metodyka	Cel	Data rozpoczęcia	Data zakończenia
<b>Badania nierandomizowane</b>							
A Phase II Trial of Bevacizumab With Carboplatin and Weekly Paclitaxel as First-Line Treatment in Epithelial Ovarian, Primary Peritoneal, and Fallopian Tube Carcinoma	NCT01097746	Rekrutacja chorych	M.D. Anderson Cancer Center	Nierandomizowane; otwarte	[REDACTED]	marzec 2010	styczeń 2012
Phase 2 Study of Bevacizumab in Combination With Carboplatin and Paclitaxel in Patients With Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma	NCT00408070	Przedwcześnie zakończone	University of Connecticut Health Center	Nierandomizowane; otwarte	[REDACTED]	październik 2006	sierpień 2009



Tytuł	Numer identyfikacyjny	Status	Sponsor	Metodyka	Cel	Data rozpoczęcia	Data zakończenia
Phase II Evaluation of Carboplatin, Paclitaxel and Bevacizumab as First Line Chemotherapy and Consolidation for Advanced Ovarian Cancer	NCT00129727	Zakończone, nieopublikowane	Massachusetts General Hospital	Nierandomizowane; otwarte	[REDACTED]	czerwiec 2005	luty 2009
A Phase I Trial Of Intravenous Paclitaxel Intraperitoneal Carboplatin And Intraperitoneal Paclitaxel Or Intravenous Docetaxel, Intraperitoneal Carboplatin, And Intraperitoneal Paclitaxel Or Intravenous Paclitaxel, Intraperitoneal Carboplatin, Intraperitoneal Paclitaxel And CTEP-Supplied Agent Bevacizumab (NSC 704865, IND 7921) In Patients With Previously Untreated Ovarian, Fallopian Tube Or Primary Peritoneal Carcinoma	NCT00085358	Zakończone, nieopublikowane	Gynecologic Oncology Group	Nierandomizowane; otwarte	[REDACTED]	czerwiec 2004	maj 2011

Tytuł	Numer identyfikacyjny	Status	Sponsor	Metodyka	Cel	Data rozpoczęcia	Data zakończenia
Phase I Study of Intraperitoneal Carboplatin With Intravenous Paclitaxel and Bevacizumab in Patients With Previously Untreated Epithelial Ovarian Carcinoma or Primary Peritoneal Carcinoma	NCT01220154	Rekrutacja chorych	Ohio State University	Nierandomizowane; otwarte	[REDACTED]	październik 2010	październik 2015
Global Study to Assess the Addition of Bevacizumab to Carboplatin and Paclitaxel as Front-line Treatment of Epithelial Ovarian Cancer, Fallopian Tube Carcinoma or Primary Peritoneal Carcinoma	NCT01239732	Rekrutacja chorych	Hoffmann-La Roche	Nierandomizowane; otwarte	[REDACTED]	grudzień 2010	listopad 2014
A Study of First Line Treatment With Avastin (Bevacizumab) in Combination With Carboplatin and Weekly Paclitaxel in Patients With Ovarian Cancer	NCT00937560	W trakcie trwania; nie rekrutuje chorych	Hoffmann-La Roche	Nierandomizowane; otwarte	[REDACTED]	czerwiec 2009	lipiec 2013

Tytuł	Numer identyfikacyjny	Status	Sponsor	Metodyka	Cel	Data rozpoczęcia	Data zakończenia
A Phase II, Open-Label, Non-Randomized, Multi-Center Pilot Study of Intravenous Taxol, Carboplatin, Bevacizumab Given Every 21 Days in Patients With Newly Diagnosed Stage III/IV Epithelial Ovarian, Fallopian Tube or Peritoneal Cancer	NCT00127920	Zakończone, nieopublikowane	Gynecologic Oncology Associates	Nierandomizowane; otwarte	[REDACTED]	sierpień 2004	sierpień 2006
[REDACTED]							
A Randomized Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel in Combination With Carboplatin With or Without Concurrent and Consolidation Bevacizumab (NSC #704865, IND #7921) in the Treatment of Primary Stage II, III or IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer	NCT01167712	Wstrzymane	Gynecologic Oncology Group	RCT; otwarte	[REDACTED]	październik 2010	luty 2012

Tytuł	Numer identyfikacyjny	Status	Sponsor	Metodyka	Cel	Data rozpoczęcia	Data zakończenia
A Phase III Clinical Trial of Bevacizumab With IV Versus IP Chemotherapy in Ovarian, Fallopian Tube, and Primary Peritoneal Carcinoma NCI-Supplied Agent(s): Bevacizumab (NSC #704865, IND #7921)	NCT00951496	W trakcie trwania; nie rekrutuje chorych	Gynecologic Oncology Group	RCT; otwarte	[REDACTED]	sierpień 2009	styczeń 2016
A Prospective Randomised Phase III Trial to Evaluate Optimal Treatment Duration of First-line Bevacizumab in Combination With Carboplatin and Paclitaxel in Patients With Primary Epithelial Ovarian, Fallopian Tube or Peritoneal Cancer	NCT01462890	Rekrutacja chorych	AGO Study Group	RCT; otwarte	[REDACTED]	listopad 2011	listopad 2018

Źródło: opracowanie własne

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## 19.6. Skale oceny jakości badań

**Tabela 61.**  
**Ocena jakości danych wg skali Jadad**

Pytanie	Odpowiedź Tak/Nie	Punktacja 1/0
Czy badanie opisano jako randomizowane?		
Czy badanie opisano jako podwójnie zaślepienie?		
Czy podano informacje o utracie pacjentów z badania i okresu obserwacji?		
Czy dodać 1 punkt za podany opis randomizacji i właściwą metodę?		
Czy dodać 1 punkt za podany opis zaślepienia i właściwą metodę?		
Czy odjąć 1 punkt za niewłaściwą metodę randomizacji?		
Czy odjąć 1 punkt za niewłaściwą metodę zaślepienia?		
<b>SUMA PUNKTÓW</b>		

**Tabela 62.**  
**Ocena jakości danych wg skali NICE**

Pytanie	Odpowiedź Tak/Nie	Punktacja 1/0
1. Czy badanie było prowadzone w więcej niż jednym ośrodku?		
2. Czy hipoteza badawcza/cel badania jest jasno opisany?		
3. Czy kryteria włączenia i wykluczenia pacjentów są sprecyzowane?		
4. Czy zostały jasno zdefiniowane punkty końcowe?		
5. Czy dane były poprawnie analizowane?		
6. Czy w opisie badania znajduje się stwierdzenie, że pacjenci byli włączani kolejno?		
7. Czy opisano jasno wyniki badania?		

Pytanie	Odpowiedź Tak/Nie	Punktacja 1/0
8. Czy wyniki przedstawiono w podziale na podgrupy pacjentów (np. wg stopnia zaawansowania choroby, charakterystyk pacjentów, innych czynników)?		
<b>SUMA PUNKTÓW</b>		

**Tabela 63.**
**Kwestionariusz Newcastle-Ottawa Scale (NOS) do oceny badań nierandomizowanych**
**SKALA OCENY JAKOŚCI BADAŃ NEWCASTLE-OTTAWA – BADANIA KOHORTOWE**

Uwaga: badanie może otrzymać najwyżej jedną gwiazdkę za każdy numerowany element skali w kategoriach „Dobór próby” i „Punkt końcowy”. W kategorii „Porównywalność” można przyznać najwyżej dwie gwiazdki.

**Dobór próby**

 1) Reprezentatywność kohorty narażonej

- w pełni reprezentatywna w odniesieniu do przeciętnego \_\_\_\_\_ (proszę wypisać) w danej społeczności \*
- w pewnym stopniu reprezentatywna w odniesieniu do przeciętnego \_\_\_\_\_ w danej społeczności \*
- określona grupa użytkowników (np. pielęgniarki, wolontariusze)
- nie określono metody doboru kohorty

 2) Dobór kohorty bez narażenia

- z tej samej co narażona kohorta \*
- z innego środowiska (z innej populacji)
- nie określono metody doboru kohorty bez narażenia

 3) Stwierdzenie narażenia

- dane pewne (np. dokumentacja zabiegu chirurgicznego) \*
- ustrukturyzowany wywiad \*
- raportowane przez chorego w formie pisemnej
- nie określono

 4) Wykazano, że badany punkt końcowy nie występował na początku badania

- tak \*
- nie

**Porównywalność**

 1) Porównywalność kohort na podstawie planu badania lub analizy

- w badaniu uwzględniono \_\_\_\_\_ (proszę wybrać najbardziej istotny czynnik) \*
- w badaniu uwzględniono dodatkowy czynnik (to kryterium można zmodyfikować tak, aby dotyczyło innego istotnego czynnika) \*

**Punkt końcowy**

 1) Ocena wystąpienia punktu końcowego

- niezależna ocena z zaślepieniem \*
- odwołanie do dokumentacji \*
- raportowane przez chorego
- nie określono

 2) Czy okres obserwacji był odpowiednio długi, aby wystąpił punkt końcowy?

- tak (proszę wybrać odpowiedni okres obserwacji dla badanego punktu końcowego) \*

b) nie
3) <u>Poprawność obserwacji kohort</u>
a) pełna obserwacja – znane losy wszystkich chorych *
b) małe prawdopodobieństwo błędu systematycznego na skutek utraty chorych z okresu obserwacji – niewielka liczba utraconych chorych - > ____ % ukończyło obserwację (proszę wybrać odpowiedni odsetek) lub odniesiono się losów chorych utraconych *
c) < ____% ukończyło obserwację (proszę wybrać odpowiedni odsetek) i brak odniesienia do losów chorych utraconych
d) nie określono

**Tabela 64.**  
**Kryteria oceny jakości danych wg wytycznych GRADE**

Rodzaj badania:
<ul style="list-style-type: none"> <li>– badanie z randomizacją = jakość wysoka</li> <li>– badanie obserwacyjne = jakość niska</li> <li>– jakiegokolwiek inne dane = jakość bardzo niska</li> </ul>
Czynniki obniżające jakość danych:
<ul style="list-style-type: none"> <li>– poważne (–1) albo bardzo poważne (–2) ograniczenie jakości badania</li> <li>– ważna niezgodność wyników (–1)</li> <li>– umiarkowana (–1) lub duża (–2) niepewność co do możliwości odniesienia danych</li> <li>– nieprecyzyjne oszacowanie efektów lub zbyt mała liczba danych (–1)</li> <li>– duże prawdopodobieństwo, że część badań na dany temat nie została opublikowana (–1)</li> </ul>
Czynniki zwiększające jakość danych:
<ul style="list-style-type: none"> <li>– silny związek pomiędzy interwencją a punktem końcowym – statystycznie istotne ryzyko względne &gt;2 (albo &lt;0,5) oszacowane na podstawie zgodnych wyników <math>\geq 2</math> badań obserwacyjnych, bez prawdopodobnych czynników zakłócających mogących zmniejszyć zaobserwowany efekt (+1)</li> <li>– bardzo silny związek pomiędzy interwencją a punktem końcowym – statystycznie istotne ryzyko względne &gt;5 (albo &lt;0,2) na podstawie danych bezpośrednich, bez poważnych zastrzeżeń co do ich wiarygodności (+2)</li> <li>– wykazanie zależności efektu od dawki (+1)</li> <li>– wszystkie prawdopodobne, ale niewzięte pod uwagę czynniki zakłócające najprawdopodobniej zmniejszyły zaobserwowany efekt (+1)</li> </ul>

**Tabela 65.**  
**Klasyfikacja doniesień naukowych odnoszących się do terapii<sup>1</sup>**

Typ badania	Rodzaj badania	Opis podtypu
Przegląd systematyczny RCT	IA	Metaanaliza na podstawie wyników przeglądu systematycznego RCT;
	IB	Systematyczny przegląd RCT bez metaanalizy;
Badanie eksperymentalne	IIA	Poprawnie zaprojektowana kontrolowana próba kliniczna z randomizacją <sup>2</sup> ;
	IIB	Poprawnie zaprojektowana kontrolowana próba kliniczna z pseudorandomizacją;

Typ badania	Rodzaj badania	Opis podtypu
	IIC	Poprawnie zaprojektowana kontrolowana próba kliniczna bez randomizacji <sup>3</sup> ;
Badanie obserwacyjne z grupą kontrolną	IIIA	Przegląd systematyczny badań obserwacyjnych;
	IIIB	Poprawnie zaprojektowane prospektywne badanie kohortowe z równoczesową grupą kontrolną;
	IIIC	Poprawnie zaprojektowane prospektywne badanie kohortowe z historyczną grupą kontrolną;
	IIID	Poprawnie zaprojektowane retrospektywne badanie kohortowe z równoczesową grupą kontrolną;
	IIIE	Poprawnie zaprojektowane badanie kliniczno-kontrolne (retrospektywne);
Badanie opisowe	IVA	Seria przypadków - badanie pretest/posttest <sup>4</sup> ;
	IVB	Seria przypadków - badanie posttest <sup>5</sup> ;
	IVC	Inne badanie grupy pacjentów;
	IVD	Opis przypadku;
Opinia ekspertów	V	Opinia ekspertów w oparciu o doświadczenie kliniczne, badania opisowe oraz raporty panelów ekspertów;

<sup>1</sup> Modyfikacja własna na podstawie: *Undertaking systemic reviews of research on effectiveness: CRD guidelines for those carrying out or commissioning reviews*. CRD report #4, University of York, York 1996.

<sup>2</sup> Kontrolowana próba kliniczna z randomizacją, ang. *randomised controlled trial*, RCT.

<sup>3</sup> Kontrolowana próba kliniczna, ang. *clinical controlled trial*, CCT.

<sup>4</sup> Badanie typu pretest/posttest – badanie opisowe ze zbieraniem danych przed zastosowaniem ocenianego postępowania i po nim.

<sup>5</sup> Badanie typu posttest – badanie opisowe ze zbieraniem danych tylko po zastosowaniu ocenianego postępowania.

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## 19.7. Badania wykluczone na podstawie pełnych tekstów

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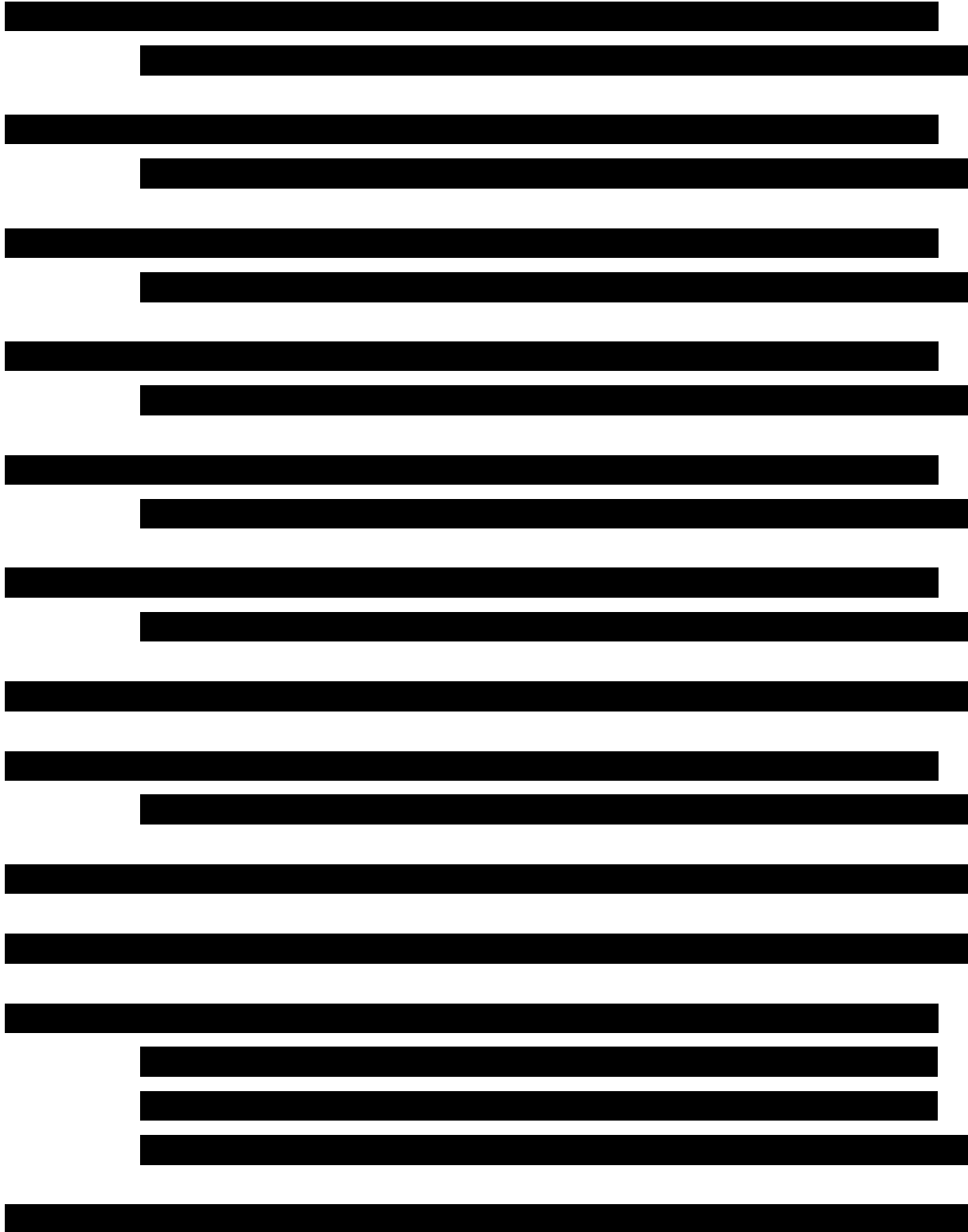
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