Market Analysis and Patient Sub-segment Identification for Glioblastoma Multiforme (GBM) Entry Strategy

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Background Research

Introduction

This report offers a comprehensive analysis of the Glioblastoma Multiforme (GBM) therapeutic area to facilitate our client's decision-making process as they contemplate entering this specialized field. Our primary focus is on understanding the structure of the GBM market, specifically identifying clinically significant patient subgroups that receive distinct treatments. The ultimate objective is to unveil distinct opportunities within this challenging and critical medical landscape.

GBM Overview

Glioblastoma Multiforme (GBM) stands as the most common and aggressive primary malignant brain tumor in adults. It originates from glial cells in the brain, particularly astrocytes. GBM is characterized by its highly invasive nature, rapid growth rate, and a high recurrence rate, making it a formidable challenge to treat. The standard treatment protocol includes surgery, radiation, and chemotherapy, with Temozolomide being a common chemotherapy drug. Despite aggressive treatment, prognosis remains bleak, with a median survival of 12-15 months.

Market Analysis

Descriptive Statistics To better understand the GBM market, here are some analysis results utilizing data of 750 participants from 150 healthcare providers.

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## [1] "Summary statistics for selected numeric variables:"
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	mean	sd	min	max	range
year_of_birth	1957.898667	12.031906	1925	1996	71
age_at_diagnosis	56.897333	12.230709	19	88	69
pct_of_tumor_mass_surgically_resected	70.098901	24.275281	10	100	90
comorbidity_count	1.126667	1.293388	0	8	8

```
## [1] "Selected categorical variables, Frequencies:"
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variable	categories	count	percent
line_of_therapy	1L	300	40%
line_of_therapy	2L	450	60%
gender	Female	259	35%
gender	Male	491	65%
race	Asian	30	4.0%
race	Black	110	14.7%
race	Hispanic	44	5.9%
race	Other	3	0.4%
race	White	563	75.1%
patient_level_of_involvement	Low	76	10%
patient_level_of_involvement	Average	382	51%
patient_level_of_involvement	High	292	39%
patient_treatment_goals	Life Quality	235	31%
patient_treatment_goals	Survival	515	69%

```
## [1] "Selected categorical variables, Chi-square test:"
```

	variable	chi_square	p_value
X-squared	race	20	0.2202206
X-squared1	patient_level_of_involvement	6	0.1991483

Comorbidities There are a number of comorbidities that can co-occur with GBM. There is a maximum of 8 comorbidities co-occurring with GBM in record. The table below listed the 5 most common comorbidities in record and their frequencies.

	Comorbidity	Frequency
14	hypertension	180
9	diabetes	138
2	anemia	117
8	copd pulmonary	86
23	renal impairment	79

Existing Regimens

1st line of therapy Regimen used in 1st line of therapy include Avastin + Irinotecan, Avastin + Lomustine, Avastin + TMZ, Avastin mono, Gliadel wafers, Lomustine mono, Other, TMZ mono. The most popular regimen used is TMZ mono, which accounts for 48.40% of all regimens recorded. The least popular regimen used is Other, specifically , Irinotecan, lomustine, which altogether accounts for 0.27% of all regimens recorded.

2nd line of therapy Regimen used in 2nd line of therapy include Avastin + Irinotecan, Avastin + Lomustine, Avastin + TMZ, Avastin mono, Gliadel wafers, Lomustine mono, Other, TMZ mono, Unknown. Excluding Unknown, the most popular regimen used is Avastin mono, which accounts for 28.89% of all regimens recorded. The least popular regimen used is Gliadel wafers, which accounts for 0.44% of all regimens recorded.

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## [1] "Regimens, Chi-square test:"
```
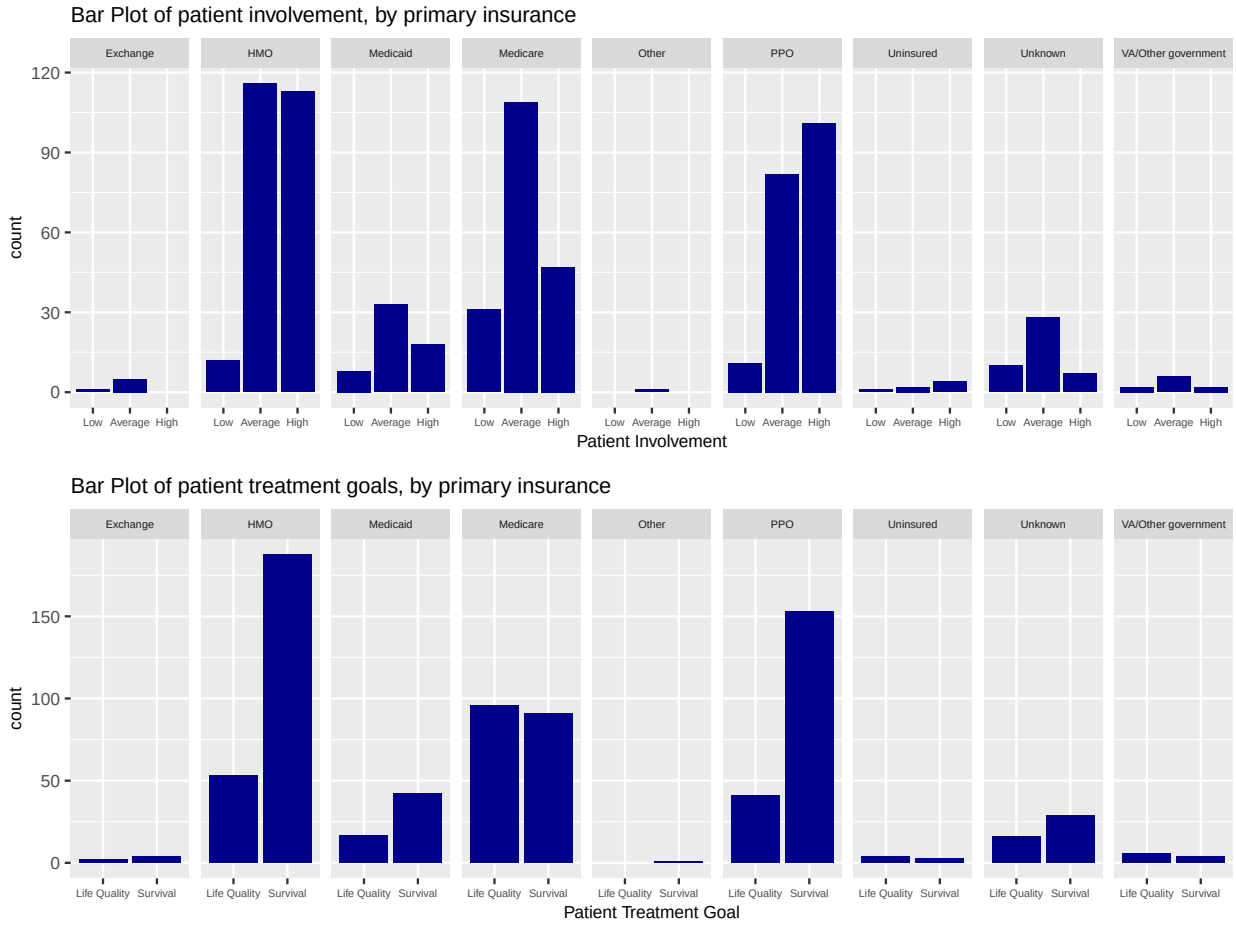

	variable	chi_square	p_value
X-squared	regimen_in_1st_line	56	0.2288520
X-squared1	regimen_in_2nd_line	63	0.2425431

Patient Behaviors & Insurance Patient's level of involvement in GBM and treatment goal differs by their age at diagnosis, their gender, their race, their line of therapy, their primary insurance, the comorbidity they have, their travel time (if less than 30 minutes), whether there is adequate support from caretaker, and the percent of tumor mass surgically resected.

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## [1] "Bivariate Logistic Regression Analysis, significant at 5% level:"
```

term	outcome	estimate	p.value
age_at_diagnosis	level_of_involvement	-0.0234654	0.0211683
raceHispanic	level_of_involvement	-2.1435191	0.0467813
patient_travel_time_lt30minYes	level_of_involvement	0.9879467	0.0016513
patient_travel_time_lt30minUnknown	level_of_involvement	-1.1882244	0.0008270
pct_of_tumor_mass_surgically_resected	level_of_involvement	0.0258449	0.0000058

term	outcome	estimate	p.value
age_at_diagnosis	treatment_goals	-0.0335301	0.0000009
genderMale	treatment_goals	0.4528791	0.0054367
line_of_therapy2L	treatment_goals	-0.3412157	0.0370748
comorbidity_count	treatment_goals	-0.1641480	0.0054494
adequate_caretaker_supportUnknown	treatment_goals	-1.2811653	0.0000958

Additionally, multiple variable logistic regression including all exposures with significant bivariate result found:

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## [1] "Multivariable Logistic Regression Analysis, Outcome = Patient's Level of Involvement:"
```
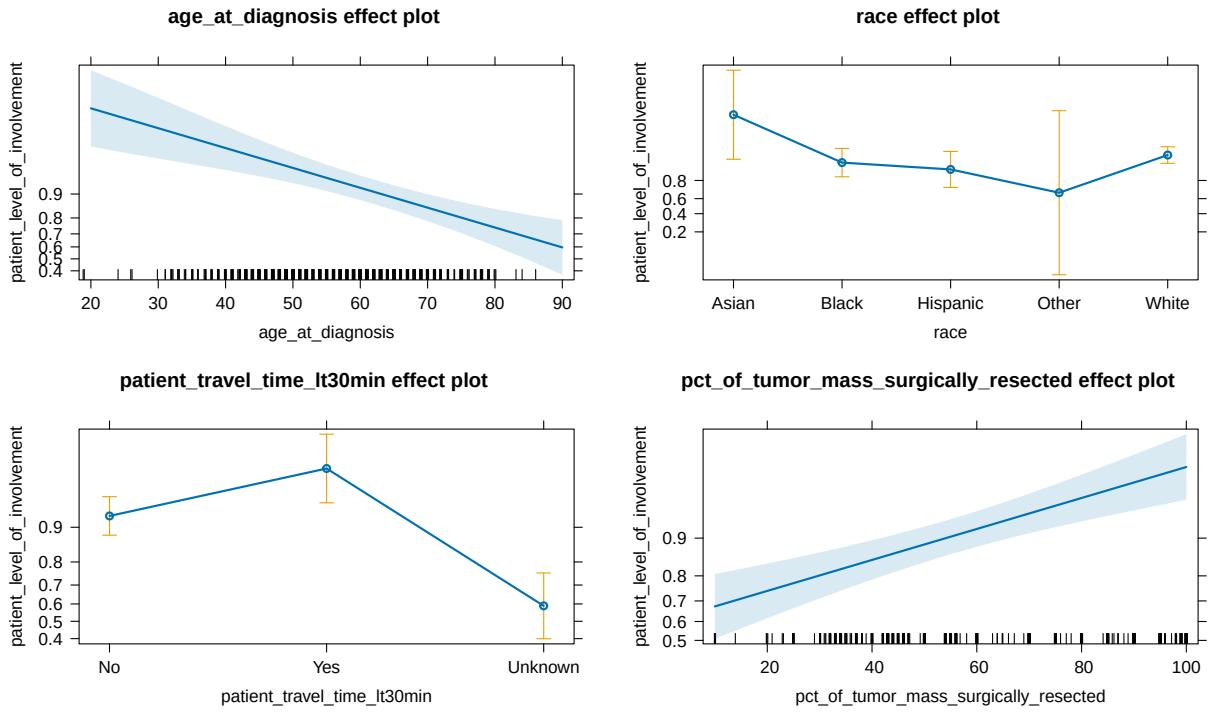

term	estimate	std.error	p.value
(Intercept)	6.0487267	1.5486831	0.0000939
age_at_diagnosis	-0.0673287	0.0151541	0.0000089
raceBlack	-2.5810227	1.2365177	0.0368582
raceHispanic	-2.9490817	1.2834332	0.0215728
raceOther	-4.2066362	2.5364882	0.0972269
raceWhite	-2.1733087	1.2025873	0.0707320
patient_travel_time_lt30minYes	1.1087538	0.4270037	0.0094154
patient_travel_time_lt30minUnknown	-2.1012914	0.4688135	0.0000074
pct_of_tumor_mass_surgically_resected	0.0332771	0.0067091	0.0000007

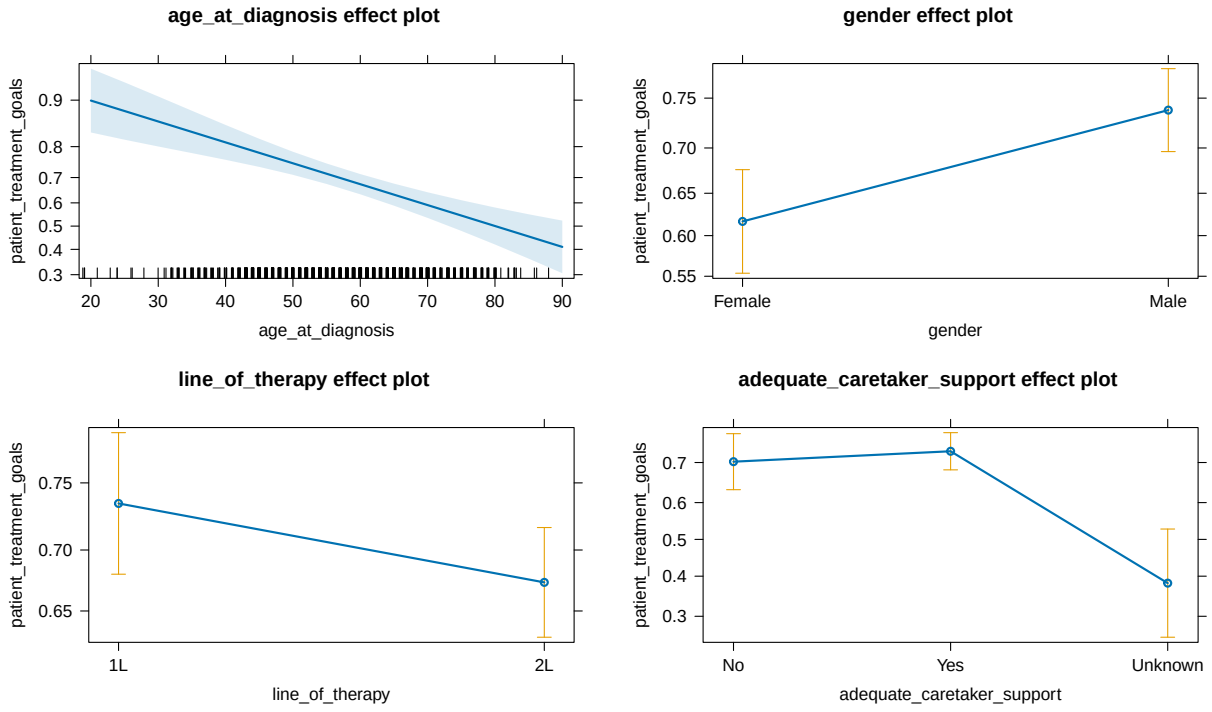
```
## [1] "Multivariable Logistic Regression Analysis, Outcome = Patient's Treatment Goals:"
```

term	estimate	std.error	p.value
(Intercept)	2.7411067	0.4435294	0.0000000
age_at_diagnosis	-0.0364637	0.0070148	0.0000002
genderMale	0.5611603	0.1708641	0.0010225
line_of_therapy2L	-0.2955515	0.1699222	0.0819760
adequate_caretaker_supportYes	0.1148266	0.1892821	0.5440881
adequate_caretaker_supportUnknown	-1.3385046	0.3423652	0.0000925

```
## [1] "Predicted Probabilities Plots, Outcome = patient involvement level"
```



[1] "Predicted Probabilities Plots, Outcome = patient treatment goals"



Discussion Questions

Market Landscape

Given the poor prognosis and limited efficacy of current treatments, there's a notable unmet need for new therapies in the GBM market. Numerous pharmaceutical and biotech companies are conducting research on new treatments, encompassing targeted therapies, immunotherapies, and personalized medicine approaches. Clinical trials are underway to evaluate various novel agents and treatment modalities.

Potential Market Opportunities

- Development of drugs with the ability to effectively cross the blood-brain barrier (BBB).
- Targeted therapies based on molecular and genetic profiling of tumors.
- Immunotherapies designed to engage the immune system to recognize and attack GBM cells.
- Advanced drug delivery systems, such as nanoparticles or convection-enhanced delivery.

Market Risks

- Stringent regulatory pathways due to the aggressive nature of GBM and past drug development failures.
- Challenges in clinical trial design related to the heterogeneity of the disease.
- Competition from existing and emerging therapies.
- Payer and reimbursement challenges due to the high costs of cancer therapies.

Competitive Landscape & Ongoing Clinical Trials

- Evaluation of current treatments, including surgery, radiation, and chemotherapy (Temozolomide).
- Identification of industry leaders, their drug candidates, and market share.
- Focused analysis on late-stage clinical trials and recent trends.
- Examination of trial results, particularly notable successes and failures.

Collaboration Opportunities & Regulatory Considerations

- Exploration of potential partnerships with research institutions, pharmaceutical, and biotech companies.
- Engagement with patient organizations.
- Thorough review of FDA and EMA guidelines for oncology drug approvals.
- Comprehension of expedited pathways such as Breakthrough Therapy and Fast Track.

Market Insights The cost of existing treatments varies significantly, ranging from surgical procedures and radiation therapy to chemotherapy drugs like Temozolomide. Costs are influenced by factors like insurance coverage, geographic location, and treatment duration. Additionally, the introduction of innovative therapies, including Tumor Treating Fields (TTF) through devices like Optune, adds complexity to the market.