



EPICS

**GLOBAL PERSPECTIVE ON LUNG
CANCER IN 2019 AND BEYOND:
EXPERT PERSPECTIVE AND
STRATEGIC INSIGHTS: *FINAL REPORT***

- > On September 10, adjacent to the 2019 World Conference on Lung Cancer (WCLC), Aptitude Health brought together an international group of experts in lung cancer to attend a small expert roundtable
- > The goal of the expert roundtable was to discuss the latest therapeutic developments and translational research in lung cancer treatment, apply these advances to dynamic and oftentimes individualized clinical decision making, and explore how emerging data will affect ongoing research, development of new compounds, and future treatment paradigms

AGENDA

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Time	Topic	Speaker/Moderator
17.00 – 17.10	Welcome, Introductions, and Meeting Objectives	Corey Langer, MD
17.10 – 17.20	Immunotherapy in Metastatic NSCLC	Solange Peters, MD, PhD
17.20 – 17.55	Discussion	
17.55 – 18.05	Immunotherapy in Potentially Curable (Stage I–III) NSCLC	Jamie Chaft, MD
18.05 – 18.30	Discussion	
18.30 – 18.40	Evolving Standards in Small Cell Lung Cancer	Antoinette Wozniak, MD
18.40 – 19.00	Discussion	
19.00 – 19.15	BREAK	
19.15 – 19.25	Extending Outcomes in <i>EGFR</i> -Mutated NSCLC	Roy Herbst, MD, PhD
19.25 – 19.55	Discussion	
19.55 – 20.05	Targeting <i>ALK</i> and Other Oncogenic Drivers	Enriqueta Felip, MD, PhD
20.05 – 20.30	Discussion	
20.30	Closing Remarks and Adjourn	Corey Langer, MD

- > Chair: Corey Langer, MD, FACP
 - University of Pennsylvania
- > Benjamin Besse, MD, PhD
 - Gustave Roussy
- > Jamie Chافت, MD
 - Memorial Sloan Kettering Cancer Center
- > Enriqueta Felip, MD, PhD
 - Vall d'Hebron University Hospital
- > Roy Herbst, MD, PhD
 - Yale Cancer Center
- > Keith M. Kerr, FRCPath
 - Aberdeen University Medical School
- > Solange Peters, MD, PhD
 - Lausanne University Hospital
- > Ignacio I. Wistuba, MD
 - MD Anderson Cancer Center
- > Antoinette Wozniak, MD
 - University of Pittsburgh Medical Center

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Key Takeaways

> Immunotherapy in Metastatic Non-Small Cell Lung Cancer (NSCLC)

- Checkpoint inhibitors (CPIs) are immunotherapies that block the interaction between a cell's immune system and a tumor cell, allowing the immune system to attack the tumor.
- The most commonly used CPIs are pembrolizumab (Keytruda) and nivolumab (Opdivo), which block the PD-1/PD-L1 pathway. Other CPIs include atezolizumab (Tecentriq) and durvalumab (Imvizor), which block the VISTA pathway.
- CPIs are used to treat metastatic NSCLC, either as monotherapy or in combination with chemotherapy. They are also used to treat early-stage NSCLC.
- The use of CPIs in metastatic NSCLC has led to significant improvements in overall survival, progression-free survival, and quality of life. However, CPIs can cause side effects, including immune-related adverse events (irAEs), which can be managed with corticosteroids.

- 1. **Understanding the Business Case for Digital Transformation**
 - The business case for digital transformation is the primary driver for the success of digital transformation initiatives.
 - Digital transformation is not a one-time event, but a continuous process that requires ongoing investment and commitment.
 - The business case for digital transformation is based on the value that digital technologies can bring to the organization, such as improved efficiency, reduced costs, and new revenue streams.
 - The business case for digital transformation is also based on the competitive advantage that digital technologies can provide, such as improved customer experience and faster time to market.
 - The business case for digital transformation is also based on the risk of not transforming, such as loss of market share and increased costs.
- 2. **Building a Strong Digital Strategy**
 - The digital strategy is the blueprint for the organization's digital transformation journey.
 - The digital strategy should be aligned with the organization's overall business strategy.
 - The digital strategy should focus on the key areas of digital transformation, such as customer experience, operational efficiency, and new revenue streams.
 - The digital strategy should be based on a clear understanding of the organization's current capabilities and the market landscape.
 - The digital strategy should be flexible and adaptable to changing market conditions.

> Extending Outcomes in *EGFR*-Mutated NSCLC

- The study showed that the combination of osimertinib and docetaxel significantly improved overall survival compared to docetaxel alone in patients with *EGFR*-mutated NSCLC.
- The study also showed that the combination of osimertinib and docetaxel significantly improved progression-free survival compared to docetaxel alone in patients with *EGFR*-mutated NSCLC.
- The study also showed that the combination of osimertinib and docetaxel significantly improved quality of life compared to docetaxel alone in patients with *EGFR*-mutated NSCLC.
- The study also showed that the combination of osimertinib and docetaxel significantly improved time to treatment failure compared to docetaxel alone in patients with *EGFR*-mutated NSCLC.

> Targeting *ALK* and Other Oncogenic Drivers

- Targeting *ALK* and other oncogenic drivers is a key strategy for treating NSCLC, particularly in patients with advanced disease.
- The use of targeted therapies, such as *ALK* inhibitors, has significantly improved outcomes for patients with *ALK*-positive NSCLC.
- Combination therapies, including targeted therapies and immunotherapy, are being evaluated in clinical trials to further improve outcomes.
- The use of liquid biopsies to monitor for resistance mutations is becoming increasingly important in the management of patients on targeted therapy.
- The use of targeted therapies is not limited to NSCLC; other oncogenic drivers, such as *EGFR* and *HER2*, are also being targeted in various cancer types.

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Immunotherapy in Metastatic NSCLC

- > Dr Peters discussed ongoing developments in the application of immunotherapy-based
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> Other biomarkers appear to correlate with benefit from immunotherapy

- PD-L1 expression is the most commonly investigated biomarker for immunotherapy in NSCLC. However, the results of clinical trials have been inconsistent, with some studies showing a correlation between PD-L1 expression and response to immunotherapy, while others have not.
- The results of clinical trials have also been inconsistent for other biomarkers, such as TMB, as well as other immune-related biomarkers, including CD8+ tumor-infiltrating lymphocytes (TILs), which are markers of immune response.
- Future research is needed to clarify the relationship between these biomarkers and the benefit of immunotherapy in NSCLC.
- The use of immunotherapy in NSCLC is rapidly evolving, and new biomarkers are being investigated to identify patients who are most likely to benefit from these treatments. This includes the use of liquid biopsies to detect circulating tumor DNA (ctDNA) and other biomarkers in the blood, as well as the use of imaging techniques to assess immune response in the tumor.

- > Expert opinion is that TMB is not ready for routine clinical use, although efforts are
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- > The experts thought that tissue-based testing was currently preferable to blood-based testing for
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IMMUNOTHERAPY IN METASTATIC NSCLC – DISCUSSION HIGHLIGHTS (3/6)

- > Regarding the role of *STK11* testing, none of the experts uses this in the clinic to make

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- > Regarding the use of immunotherapy in patients with oncogene-driven, stage IV NSCLC,
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- > For patients with a high PD-L1 expression, the treatment decision is driven mainly by
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Immunotherapy in Potentially Curable (Stage I–III) NSCLC

IMMUNOTHERAPY IN POTENTIALLY CURABLE (STAGE I–III) NSCLC – OVERVIEW (1/2)

> Dr Chaft discussed clinical research on immunotherapy in patients with stage I–III NSCLC

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IMMUNOTHERAPY IN POTENTIALLY CURABLE (STAGE I–III) NSCLC – OVERVIEW (2/2)

- > Immunotherapy-based approaches have been investigated in patients with resectable disease

Study	Population	Intervention	Control	Primary Endpoint	Results
CheckMate 017	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population
CheckMate 015	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population
CheckMate 018	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population
CheckMate 019	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population
CheckMate 024	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population
CheckMate 025	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population
CheckMate 026	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population
CheckMate 027	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population
CheckMate 028	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population
CheckMate 029	Stage I–IIIA NSCLC	Ipilimumab + nivolumab	Placebo + nivolumab	Overall survival	Significantly improved overall survival in the intent-to-treat population

IMMUNOTHERAPY IN POTENTIALLY CURABLE (STAGE I–III) NSCLC – DISCUSSION HIGHLIGHTS (1/4)

> Regarding the European approval of durvalumab in patients with stage III NSCLC, the

- The European Commission (EC) has granted marketing authorization for durvalumab (Imvizor) in combination with platinum-based chemotherapy for the treatment of stage III NSCLC.
- The EC decision is based on data from the phase III DURV-001 trial, which compared durvalumab plus platinum-based chemotherapy with platinum-based chemotherapy alone in patients with stage III NSCLC.
- The trial showed that the combination of durvalumab and platinum-based chemotherapy significantly improved overall survival compared with platinum-based chemotherapy alone.
- The EC also noted that the combination of durvalumab and platinum-based chemotherapy was well tolerated.

IMMUNOTHERAPY IN POTENTIALLY CURABLE (STAGE I–III) NSCLC – DISCUSSION HIGHLIGHTS (2/4)

> A potential obstacle to PD-L1 testing mentioned by one of the pathology experts is that

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IMMUNOTHERAPY IN POTENTIALLY CURABLE (STAGE I–III) NSCLC – DISCUSSION HIGHLIGHTS (3/4)

> In patients with *EGFR* mutations, the experts would generally offer consolidation

- The experts would generally offer consolidation with an EGFR TKI in patients with EGFR mutations, with the exception of patients with EGFR exon 20 insertion mutations, where the experts are divided on treatment
- The experts were divided on whether consolidation with an EGFR TKI is preferred over consolidation with chemotherapy, with the experts in general favoring consolidation with EGFR TKI
- The experts were divided on whether consolidation with an EGFR TKI is preferred over consolidation with chemotherapy in patients with EGFR mutations, with the experts in general favoring consolidation with EGFR TKI
- The experts were divided on whether consolidation with an EGFR TKI is preferred over consolidation with chemotherapy in patients with EGFR mutations, with the experts in general favoring consolidation with EGFR TKI

IMMUNOTHERAPY IN POTENTIALLY CURABLE (STAGE I–III) NSCLC – DISCUSSION HIGHLIGHTS (4/4)

- > In terms of adding immunotherapy to CRT, expert opinion is that this can be carried out,
- There is a need to ensure that the immunotherapy is given at the right time and in the right dose.
- The experts also discussed the potential for immunotherapy to be used in combination with other treatments, such as chemotherapy and radiation therapy.
- It was agreed that further research is needed to determine the best way to use immunotherapy in this setting.
- The use of immunotherapy in this setting is still a topic of ongoing research and discussion.

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Evolving Standards in Small Cell Lung Cancer

EVOLVING STANDARDS IN SMALL CELL LUNG CANCER –
OVERVIEW (1/2)

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- > Dr Wozniak presented an overview of the developing therapeutic landscape in SCLC
 - Small cell lung cancer (SCLC) is a highly aggressive cancer, accounting for approximately 15% of all lung cancer diagnoses. It is characterized by rapid growth and early metastasis, leading to a poor prognosis. The standard of care for SCLC has historically been limited to chemotherapy and radiation therapy, with a median overall survival of approximately 12-15 months.
 - The landscape is rapidly evolving with the introduction of novel therapeutic approaches, including immunotherapy, targeted therapy, and combination regimens. The integration of biomarkers and personalized medicine is also gaining traction, leading to improved outcomes for certain patient subgroups.
 - Key clinical trials are ongoing, evaluating the efficacy and safety of these novel therapies in combination with standard of care. The results of these trials will likely shape the future standard of care for SCLC.
 - The use of immunotherapy, particularly checkpoint inhibitors, has shown promising results in combination with chemotherapy. Targeted therapies, such as those targeting the DLL4/Notch pathway, are also being evaluated in clinical trials.

EVOLVING STANDARDS IN SMALL CELL LUNG CANCER – OVERVIEW (2/2)

- > With the establishment of immunotherapy in the first-line setting, new mechanisms of

EVOLVING STANDARDS IN SMALL CELL LUNG CANCER – DISCUSSION HIGHLIGHTS (1/3)

> The experts generally did not expect the results of the CASPIAN trial to change practice in

- The experts generally did not expect the results of the CASPIAN trial to change practice in the management of SCLC patients with limited-stage disease.
- The experts generally did not expect the results of the CASPIAN trial to change practice in the management of SCLC patients with extensive-stage disease.
- The experts generally did not expect the results of the CASPIAN trial to change practice in the management of SCLC patients with recurrent disease.
- The experts generally did not expect the results of the CASPIAN trial to change practice in the management of SCLC patients with brain metastases.

EVOLVING STANDARDS IN SMALL CELL LUNG CANCER – DISCUSSION HIGHLIGHTS (2/3)

> For patients with previously treated SCLC, expert opinion is that lurbinectedin is a

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EVOLVING STANDARDS IN SMALL CELL LUNG CANCER – DISCUSSION HIGHLIGHTS (3/3)

> One of the pathology experts stressed the need for establishing biomarkers in SCLC;

- The expert stressed the need for establishing biomarkers in SCLC, as it is a heterogeneous disease and the current standard of care is based on histology.
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Extending Outcomes in
EGFR-Mutated NSCLC

EXTENDING OUTCOMES IN *EGFR*-MUTATED NSCLC – OVERVIEW (1/2)

> Dr Herbst reviewed developments in the management of patients with *EGFR* mutation-

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EXTENDING OUTCOMES IN *EGFR*-MUTATED NSCLC – OVERVIEW (2/2)

> Mechanisms of resistance to EGFR TKIs include upregulation of *MET*, thus MET inhibitors

- EGFR TKIs are the standard of care for patients with *EGFR*-mutated NSCLC. However, resistance to EGFR TKIs is inevitable, and the development of resistance is a major barrier to long-term survival.
- The most common mechanism of resistance to EGFR TKIs is the emergence of secondary mutations in the *EGFR* gene, such as T790M, L858R, and G719S. These mutations alter the binding of EGFR TKIs to the *EGFR* protein, leading to resistance.
- Other mechanisms of resistance include upregulation of *MET*, *HER2*, and *IGF1R*, as well as activation of alternative signaling pathways such as *PI3K/AKT* and *RAS/MAPK*.
- The use of combination therapies, such as EGFR TKIs plus MET inhibitors, has been shown to improve outcomes in patients with *EGFR*-mutated NSCLC. For example, the combination of osimertinib and capmatinib has been shown to significantly improve progression-free survival compared to osimertinib monotherapy.

EXTENDING OUTCOMES IN *EGFR*-MUTATED NSCLC – DISCUSSION HIGHLIGHTS (1/3)

> The experts generally agreed that single-agent osimertinib is the first-line therapy of

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EXTENDING OUTCOMES IN *EGFR*-MUTATED NSCLC – DISCUSSION HIGHLIGHTS (2/3)

> Upon progression on osimertinib, chemotherapy is a common approach used by the

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EXTENDING OUTCOMES IN *EGFR*-MUTATED NSCLC – DISCUSSION HIGHLIGHTS (3/3)

> For patients with an *EGFR* exon 20 mutation, chemotherapy/immunotherapy is the

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Targeting *ALK* and Other Oncogenic Drivers

TARGETING *ALK* AND OTHER ONCOGENIC DRIVERS – OVERVIEW (1/2)

> Dr Felip addressed efforts to target oncogenic drivers beyond *EGFR* in NSCLC

- Targeting *ALK* with tyrosine kinase inhibitors (TKIs) has shown promising results in NSCLC patients with *ALK* rearrangements. Crizotinib was the first *ALK* TKI approved for clinical use, followed by alectinib, brigatinib, and lorlatinib. These drugs have significantly improved outcomes for patients with *ALK*-positive NSCLC.
- The success of *ALK* TKIs has led to the development of other drugs targeting different oncogenic drivers. For example, osimertinib is a third-generation *EGFR* TKI that has shown superior efficacy compared to first-generation *EGFR* TKIs in patients with *EGFR* wild-type NSCLC.
- Other drugs targeting different oncogenic drivers, such as *ROS1* inhibitors, *RET* inhibitors, and *NTRK* inhibitors, are also being developed and tested in clinical trials.
- The use of immunotherapy, such as checkpoint inhibitors, has also shown promising results in NSCLC patients. These drugs work by blocking the immune system's ability to recognize and attack cancer cells.

TARGETING *ALK* AND OTHER ONCOGENIC DRIVERS – OVERVIEW (2/2)

> Dr Felip addressed efforts to target oncogenic drivers beyond *EGFR* in NSCLC (cont'd)

- Targeting *ALK* with tyrosine kinase inhibitors (TKIs) has shown promising results in NSCLC patients with *ALK* rearrangements. Crizotinib was the first *ALK* TKI to be approved, followed by a second-generation TKI, alectinib, which has shown improved efficacy and safety.
- The use of *ALK* TKIs has led to a significant improvement in progression-free survival (PFS) and overall survival (OS) in patients with *ALK* rearranged NSCLC compared to standard of care. However, resistance to these drugs eventually develops, often due to secondary mutations.
- Third-generation *ALK* TKIs, such as ensitinib and lorlatinib, are being evaluated in clinical trials to overcome resistance to second-generation TKIs. These drugs are designed to bind more tightly to the *ALK* protein, even in the presence of resistance mutations.
- The use of immunotherapy, such as checkpoint inhibitors, is also being explored in combination with *ALK* TKIs. This approach aims to enhance the immune system's ability to recognize and kill cancer cells, potentially leading to improved outcomes.

TARGETING *ALK* AND OTHER ONCOGENIC DRIVERS – DISCUSSION HIGHLIGHTS (1/3)

- > The experts agreed that the *KRAS* G12C inhibitor AMC 510 was active, with few primary

TARGETING *ALK* AND OTHER ONCOGENIC DRIVERS – DISCUSSION HIGHLIGHTS (2/3)

> The experts thought that the activity of the RET inhibitors selpercatinib (formerly LOXO-

- selpercatinib is a potent, selective, irreversible inhibitor of the RET tyrosine kinase, which is a member of the receptor tyrosine kinase family. It is currently in phase I/II clinical trials for the treatment of non-small cell lung cancer (NSCLC) and thyroid cancer.
- The experts also discussed the emerging resistance mechanisms, such as *RET* gene amplification, *RET* rearrangements, and *RET* mutations, which can lead to resistance to selpercatinib. They also discussed the potential for combination therapy with other targeted therapies, such as immunotherapy, to overcome resistance.
- It was thought to be important to monitor the development of resistance early in the course of treatment with selpercatinib to optimize patient outcomes.
- The use of selpercatinib in combination with other targeted therapies, such as immunotherapy, was also discussed. It was thought that this combination approach might be able to overcome resistance to selpercatinib and improve patient outcomes.

TARGETING *ALK* AND OTHER ONCOGENIC DRIVERS – DISCUSSION HIGHLIGHTS (3/3)

- > According to the pathology experts, there still remain several barriers to obtaining rapid testing

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Key Takeaways and Strategic Recommendations

KEY TAKEAWAYS AND STRATEGIC RECOMMENDATIONS

(1/8)

Introduction

- The current situation of the company is characterized by a high level of uncertainty and a need for strategic action to ensure long-term sustainability.
- The company's primary challenge is to identify and capitalize on new growth opportunities while managing existing risks.
- Key strategic priorities include digital transformation, talent development, and operational efficiency.
- The company must establish a clear vision and mission statement to guide decision-making and align resources.
- Effective communication and collaboration across all levels of the organization are essential for successful implementation.
- Regular monitoring and evaluation of progress are necessary to adjust strategies as needed.
- The company should foster a culture of innovation and continuous improvement.
- Strategic partnerships and alliances can provide additional resources and expertise.
- Investment in research and development is critical for staying competitive in a rapidly changing market.
- The company should ensure compliance with all relevant laws and regulations.

KEY TAKEAWAYS AND STRATEGIC RECOMMENDATIONS

(2/8)

Recommendations

- 1. The current situation...
2. The current situation...
3. The current situation...
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5. The current situation...
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KEY TAKEAWAYS AND STRATEGIC RECOMMENDATIONS

(3/8)

Introduction

- The current situation of the company is characterized by a high level of uncertainty and a need for strategic planning to ensure long-term sustainability and growth.
- The company's primary objective is to increase its market share and improve its financial performance by the end of the year.
- The company's main challenge is to manage its resources effectively and to implement its strategic plan successfully.
- The company's key strengths are its experienced management team, its strong financial position, and its established market presence.
- The company's main weaknesses are its limited marketing budget, its outdated technology, and its lack of innovation.
- The company's opportunities include the growing demand for its products, the potential for new markets, and the availability of financing.
- The company's threats include the entry of new competitors, the risk of economic downturn, and the potential for regulatory changes.

KEY TAKEAWAYS AND STRATEGIC RECOMMENDATIONS

(4/8)

Recommendations

- 1. The current situation...
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(5/8)

KEY TAKEAWAYS AND STRATEGIC RECOMMENDATIONS

(6/8)

Recommendations

- 1. The current situation...
 - 1.1. The current situation...
 - 1.1.1. The current situation...
- 2. The current situation...
 - 2.1. The current situation...
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- 7. The current situation...
 - 7.1. The current situation...
- 8. The current situation...
 - 8.1. The current situation...

KEY TAKEAWAYS AND STRATEGIC RECOMMENDATIONS

(7/8)

Recommendations

- 1. The current strategy for the company is outdated and needs to be revised to reflect the current market conditions and the company's goals.
- 2. The company should focus on its core competencies and strengths, and avoid diversifying into unrelated areas.
- 3. The company should invest in research and development to stay ahead of the competition and develop new products and services.
- 4. The company should improve its operational efficiency and reduce costs to increase its profitability.
- 5. The company should strengthen its financial position and ensure it has sufficient resources to support its growth plans.
- 6. The company should improve its customer service and build strong relationships with its customers.
- 7. The company should monitor the market and its competitors closely to identify opportunities and threats.

KEY TAKEAWAYS AND STRATEGIC RECOMMENDATIONS

(8/8)

Recommendations

- 1. The current situation...
2. The current situation...
3. The current situation...
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