Data driven Computational Mechanics at EXascale

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Table of Contents

1. Introduction

DCoMEX project employs novel HPC-enhanced Linear Algebra and Machine Learning (ML) methods in order to predict and monitor tumours growth and response to immunotherapy (DCoMEX-BIO), and design innovative materials and structures (DCoMEX-MAT). The main objective is to develop simulation software integrated with HPC methods to serve as a commercial tool for i) radiologists/medical doctors to differentiate responders from non-responders to immunotherapy protocols and make personalized/customised therapy decisions (DCoMEX-BIO) and ii) Engineers in construction and materials to design and virtual test new material compositions (DCoMEX-MAT).

Both of this software requires further development after the project's end before commercialization for: 1. Further improvement and optimization and 2. Development of user-friendly GUIs. To this purpose additional funding will be seeked via applications for research grants, both national and international, a number of which has already been submitted by members of the consortium. At the present state, and after an extensive market research, the consortium realized that the competition in software products related to materials and structures is very high, with new products launched and supported by established parties and companies in the field, such as ANSYS and ABAQUS. Even though DCoMEX-MAT includes significant innovations, especially in the HPC and ML related technologies, it is foreseen that it will be extremely hard to effectively position DCoMEX-MAT in the market. On the contrary, as will be analyzed below in detail, DCoMEX-BIO has a large potential with respect to current market competition. Therefore, the consortium has decided to focus on DCoMEX-BIO and put all efforts in taking the steps further to evolve it.

Focusing on the DCoMEX-BIO commercialization plan, this may involve patent development and licensing and establishing a spin-off company and or partnering with industrial players. Additional strategies include attracting venture capitalists and considering licensing or co-development with industrial partners. The Minimum Viable Product (MVP) targets end-users like radiologists and oncologists in the EU for a small-scale trial, evaluating technical aspects and generating interest from potential investors or partners in oncology, biotech and industry. The general plan is at the end to construct a joint venture formed by DCoMEX members and the relevant SMEs that will own the product. To this purpose, we are already in the process of signing a MoU with 2 European SMEs (NCOMP, AnaBiosi-Data Ltd).

In this report, we first analyze the external macroenvironment so that to reveal threats (risks) and opportunities. Then, bearing in mind the characteristics of the project we present a SWOT analysis, which is followed by a global market overview in the related industries. This is followed by a strategy section where options for monetization and go-to-market are presented. Thereafter, the report analyzes the business opportunity in the EU and sets-up a strategic commercialization plan to achieve it.

2. Macroenvironment Analysis

As markets and industries are continuously affected by regional and global drivers and trends, it is of paramount importance to analyze and assess the impact exerted by various aspects of the macro-environment on the DCoMEX-BIO. Most probable related markets are: (a) Biomarkers, (b) ultrasound SWE, and (c) AI and simulation software for predictive medical treatments and image processing (MRI). This section provides a market overview based on PESTEL's approach by looking into Political, Economic, Social, Technological, Environmental and Legal/Regulatory aspects (PESTEL) **[**1**]** and their impact and hence the prospects of exploiting the results of the DCOMEX Project.

2.1 Political/Regulatory

Political factors significantly influence the adoption and regulation of simulation-based predictive technology in personalized medicine. Challenges persist due to an inadequate regulatory framework that doesn't align well with the complexity of simulation-enhanced and biomarkers-based diagnostic tests integral to personalized medicine. Current regulatory systems are more suited for simpler diagnostic tests and lack clear standards and processes for evaluating and regulating new diagnostic tools. Additionally, reimbursement systems in many countries do not adequately reflect the value of these tests, hindering their development and adoption in healthcare systems. To address these challenges, there's a need to develop transparent and consistent policies regarding the regulation and reimbursement of molecular diagnostic tests.

In this respect, the European Medicines Agency (EMA) is working on new regulatory processes to couple tests and treatments. Guidelines from the EMA focus on biomarkers and emphasize the importance of biomarkers in clinical evaluations of anticancer medicinal products, including their role in confirmatory and exploratory studies for identifying appropriate target populations.

The study of (Bakker et al., 2022) **[2]**, examined EMA's qualification of novel methodologies for medicine development procedures between 2008 and 2020, focusing on biomarker qualification. Regulatory qualification of biomarkers is seen as crucial for harmonized use across medicine developers, fostering personalized medicine. The EMA's biomarker qualification process supports applications, with a shift towards general-use biomarkers rather than those linked to specific medicine compounds. Biomarkers, serving predictive or prognostic roles, enhance precision medicine by identifying patients likely to benefit or be harmed by a therapeutic agent. The EMA's Regulatory Science Strategy emphasizes supporting precision medicine and biomarkers. The introduced qualification procedure since 2008 aids innovative development methods, including biomarkers. The **oncology field**, often considered a **pioneer in biomarker use**, mainly features imaging, soluble, and performance score biomarkers. Although successful biomarker-guided cancer treatments exist, only a limited number of oncology biomarkers undergo EMA qualification procedures.

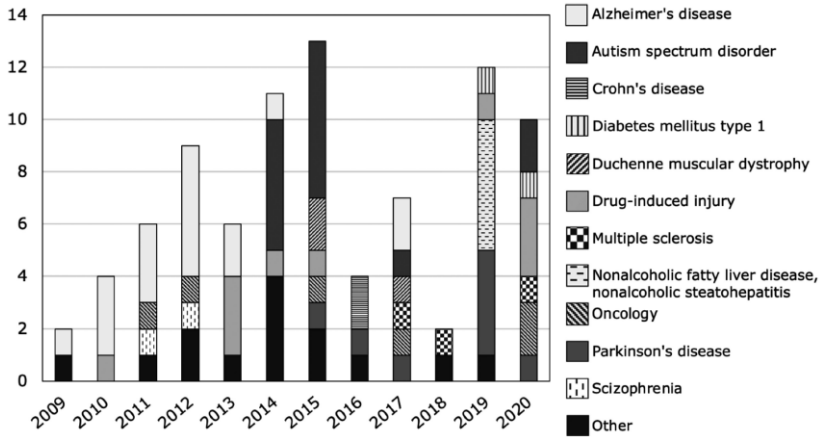

Figure 1: Number of biomarker procedures per disease or disease areas for which they were proposed over time from 2008 to 2020. (Bakker et al., 2022)

It is evident from Figure 1 that in 2020 a 20% of proposed biomarkers to EMA qualification procedures are fell under the oncology sector. The political landscape in Europe positively influences biomarker technology and cancer care through initiatives like Europe's Beating Cancer Plan (EBCP). (Europe's Beating Cancer Plan) **[3].** A significant development, and very much relevant to this project, is the European Cancer Imaging Initiative, a flagship of EBCP leveraging artificial intelligence (AI) and digital twin technologies for cancer diagnosis and treatment. This initiative aims to create a federated infrastructure of cancer imaging data accessible to clinicians, researchers, and innovators across Europe. It intends to merge scattered cancer imaging datasets from various repositories, fostering the development and testing of AI-based tools for diagnosis and treatment. European Federation of Cancer Images (EUCAIM), part of this initiative, plans to connect numerous data providers, deploy AI algorithms, and include over 100.000 cancer cases by 2025, with a focus on both common and rare cancers. This political emphasis on leveraging AI and data accessibility reflects a push for innovation in cancer care and emphasizes the importance of collaborative efforts across countries and clinical sites in Europe. The EBCP places a strong emphasis on digital transformation and the potential benefits of leveraging real-world data using advanced technologies like AI and High-Performance Computing, is also aligned with the Project's goal of creating a software product for measuring deep learning-derived SWE biomarkers. The plan also emphasises on the importance of electronic health records, data sharing, and compliance with EU data protection rules. DCoMEX-BIO has great potential to contribute to the above initiative, after a few years when the collective repository of cancer cases and SWEs stored in its database acquires a critical number.

In summary, the DCoMEX-BIO market growth is significantly impacted by regulatory factors shaping the adoption and regulation of digital technology in personalized medicine. Challenges persist due to an inadequate regulatory framework unsuitable for the complexity of simulation and biomarker-based diagnostic tests, hindering their development and integration into healthcare settings. The need for transparent policies in regulation and reimbursement is crucial. Initiatives aim to merge scattered cancer imaging datasets across Europe, fostering AI-based tools for diagnosis and treatment, emphasizing the importance of collaborative efforts and data accessibility. The political landscape's push for innovation and collaboration significantly shapes in a positive manner the market prospects for the project, highlighting the need for adaptable regulatory procedures and fostering collaborative initiatives to drive its adoption in personalized medicine. EBCP provides a fertile soil for the adoption of catting-edge technologies in cancer treatment and diagnosis. The establishment of a Knowledge Centre on Cancer and initiatives such as the European Cancer Imaging Initiative directly contributes to the project's objectives by coordinating scientific initiatives, disseminating best practices, and fostering collaboration in cancer research.

Overall, EU aims to adopt new technologies to support personalized treatment and predictive medicine for cancer treatment. While the current regulatory framework does not fully support the new technology, it is expected in the medium to long term to do so.

2.2 Economic Factors

The adoption of simulation-based technologies in the biomedical industry faces challenges, prompting a need for new business models adaptable to segmented markets. The European Union and individual countries support technological advancements in predicting cancer treatments through financial aid and initiatives like research grants.

The EBCP allocates substantial financial resources, with a total of €4 billion earmarked for cancer-related actions, a significant portion of which is derived from the EU4Health program, amounting to €1.25 billion. This substantial funding encompasses diverse initiatives such as the 'EU Mobile App for Cancer Prevention', the 'EU Network of comprehensive Cancer Centres', 'Helping Children with Cancer', 'Better Life for Cancer Patients', the 'Knowledge Centre on Cancer', and 'EU Inter-specialty Training'. Additionally, other funding avenues within the Horizon Europe Framework Programme, Erasmus+, European Institute for Technology, and Marie Skłodowska-Curie actions allocate substantial amounts for education, training, research, and digital innovation related to cancer, potentially benefiting the development and implementation. Cohesion Policy Funds, especially the European Regional Development Fund, Cohesion Fund, and European Social Fund Plus, offer support to Member States for enhancing their health systems, potentially investing in oncology infrastructure and telemedicine. Furthermore, the Recovery and Resilience Facility, a part of the 'Next Generation EU' budget, may aid in financing health infrastructure, digital healthcare transformation, and medical manufacturing capacity, including potential investments in cancer care. Additionally, the InvestEU program provides avenues for loans and equity financing that can be utilized for innovative health products, services, and care models.

However, although there is political and financial support in researching new technologies and ventures, the quest for new molecular and simulation-based biomarkers remains complex and costly, often exceeding the capabilities of individual entities despite

collaborative infrastructures for knowledge sharing. Progress in biomarker discovery and validation is slow and less efficient than desired. *(OECD)* ***[4].***

On the other hand, the cost on the economy for cancer treatment, unfortunately is on a growth trajectory. For instance, in Greece, the economic burden of metastatic breast cancer (mBC) is substantial and has been steadily increasing, with an estimated annual cost of €90mil. The primary cost driver is the drug acquisition cost of disease-specific treatments, constituting 80% of the total cost. The management cost per mBC patient per year is estimated at circa €50 thousand. Thus, the economic strain highlights the need for new therapeutic options, ideally supported by predictive simulations and biomarkers (Stafylas et al., 2022) **[5].**

Similarly, in Cyprus, breast cancer is prevalent, as 1/3 of women cancer cases are diagnosed with breast cancer and this matter of fact is despite emphasis on timely diagnosis, and the increase in the age limit for participation in screening programs from 50 to 69 years to 45 to 74 years. Mammograms have increased by 25.4%, totaling 17,214 in 2022. In Cyprus, ultrasound prices are in a range of €60 - €100, while the country leads in the number of CT and MRI scanners per 100.000 inhabitants in Europe. Health spending in Cyprus remains notably lower (almost 50%) than the EU average, with EUR 1.881 per capita in 2019 compared to the average EUR 3.523 for the EU as a whole. In response, in 2019 the country implemented a revamped General Healthcare System to address system inefficiencies, such as resource imbalance and high out-of-pocket payments. (European Commission 2021). **[6].** However, as already stated, despite a national breast cancer screening program, Cyprus records low screening rates, with only 31% of women aged 50-69 screened for breast cancer in 2019, far below the EU average of 59%. Fragmentation in the healthcare system and alternative breast examinations during cervical cancer screenings may contribute to these lower rates. The diagnostic imaging sector, however, operates with light regulation, leading to potential overuse driven by prices and General Practitioners referrals without monitoring and control mechanisms. This unregulated environment highlights challenges in maintaining clinically justified examinations and calls for improved oversight in the diagnostic imaging sector.

In summary, DCOOMEX-BIO market is influenced by economic factors shaping digitalization and biomarker technology. Industrial challenges demand adaptable business models within evolving healthcare systems focusing on targeted therapies. The move towards personalized care creates segmented markets, urging diversified strategies or backing for molecular diagnostics. Financial support from the EU, like Horizon Europe's backing for EIC Work Programme 2023, aids novel biomarker-based assays for personalized cancer treatments. However, despite infrastructure fostering biomarker discovery, the costly quest for new biomarkers impedes efficiency. The diagnostic imaging sector's unregulated environment poses challenges, highlighting the necessity for improved oversight. These economic and regulatory intricacies impact the DCOMEX-BIO market entry by emphasizing the need for cost-effective and innovative solutions.

2.3 Social Factors

Social factors exert a significant influence on digital technology and biomarkers adoption in Cyprus, Greece and across Europe. Privacy concerns surrounding genetic and biomarker-based tests demand attention. Adoption in clinical settings hinges on seamless integration into physicians' procedures. Greece, with a growing aging population vulnerable to chronic diseases, anticipates a surge in demand for ultrasound devices.

Cancer survivors face numerous treatment-related side effects, impacting their quality of life significantly. Long-term complications, including cognitive function impairment and emotional distress, correlate with survivors' age, education level, and treatment settings**.** (Yfantis at al., 2020) **[7].** These varied social factors underscore the need for improved screening programs and comprehensive support systems to address the diverse challenges faced by breast cancer patients and influence biomarker technology adoption.

The DCOMEX-BIO market penetration is impacted by prevailing social factors. Privacy concerns regarding genetic and biomarker tests necessitate careful attention, influencing trust and acceptance among users. Integration into existing clinical practices is crucial for successful adoption, ensuring seamless incorporation into physicians' routines (e.g. adoption of patients consents). Despite lower healthcare spending in Cyprus compared to the EU average, efforts to revamp the healthcare system could open avenues for innovative technologies like biomarkers and AI driven decisions. The significant impact of treatment-related side effects on breast cancer survivors' quality of life highlights the importance of advanced diagnostic tools like biomarkers to tailor treatments and mitigate adverse effects. Addressing these social factors through improved screening programs and comprehensive support systems can bolster biomarker technology adoption.

2.4 Technological Factors

Technological advancements profoundly influence digital and scanning technologies. Governments across Europe incentivize industrial research through tax incentives, encouraging establishments to develop advanced imaging facilities, like ultrasound devices (Mordor Intelligence) **[8].** Key players are launching innovative products, amplifying market growth. Recent launches, such as ReCor Medical's Paradise ultrasound renal denervation system in Germany, and GE Healthcare's Vscan Air, depict the dynamic landscape. However, challenges persist due to rising demand for refurbished imaging devices and a shortage of skilled personnel. The trend toward portable ultrasound devices in healthcare settings, including point-of-care treatments and home usage, continues to surge due to their ease of use and precision. Technological strides, including 3D and 4D imaging, amplify their applications, especially in emergency care and pre-medicine. Notably, certifications like Clarius' CE mark for ultra-portable wireless scanners and releases like Mindray Medica's ME series enhance clinical support during critical cases. Recent milestones, such as Clarius' CE mark for new ultrasound scanners and ReCor Medical's Paradise system launch, underscore the continuous innovation shaping the European ultrasound device market.

The global Radiology Information Systems (RIS) market is propelled by healthcare IT and digital advancements, expanding applications of RIS, and the rise in minimally invasive treatments alongside a growing elderly population. Technical innovations and increased demand for computerized medical diagnosis and imaging further drive opportunities in this sector. Challenges, however,

include a scarcity of trained IT professionals, high treatment costs, and interoperability issues hampering RIS market growth, Data Bridge Market Research. (2021) **[9].**

The convergence of massive data sets and AI integration is set to revolutionize patient monitoring and outcomes, presenting a vital opportunity for pharmaceutical companies to leverage emerging data sources. Yet, companies lack comprehensive strategies for collaborations, navigating decisions between academic medical centres, community networks, and patient advocacy groups to access diverse data sets. Challenges persist in standardizing cancer stage assessment in electronic health records, hindering the creation of reliable data sets. Access to data for R&D remains a focal point for all involved parties. Digital portals, exemplified by studies at institutions like Memorial Sloan Kettering Cancer Centre, exhibit tangible benefits for patients undergoing chemotherapy, improving survival rates. While academic medical centres drive advanced practices and trial development, community networks serve the majority of patients, emphasizing their pivotal role in healthcare advancements, (PwC) **[11].**

Technological advancements significantly shape cancer-related technologies across Europe, transforming oncology treatment paradigms. Biomarker tests empower oncologists with precise treatment decisions based on molecular characteristics, enhancing response rates and treatment durations. The biomarker landscape has evolved, introducing tumour-agnostic biomarkers and liquid biopsies, facilitating tailored treatments beyond traditional organ-specific approaches. Next Generation Sequencing enables extensive mutation analysis, enabling tumour-agnostic treatments driven by declining sequencing costs. Liquid biopsies offer less invasive yet comprehensive biomarker analysis, revolutionizing testing methodology and enhancing patient comfort.

Immunotherapy, encompassing diverse treatments, including checkpoint inhibitors and mRNA vaccines, has redefined standards of care across indications, notably replacing conventional chemotherapies in some areas. Personalized mRNA cancer vaccines, leveraging individual tumour mutations, represent a targeted therapy revolution. The trend towards personalized medicine extends to predictive tests for cancer risks and tailored therapies, reflecting a transformative shift in oncology. (Ipsos Global Oncology Centre of Expertise 2023) **[11].**

Moreover, ongoing R&D collaborations aim to enhance cancer diagnosis and treatment efficiency by identifying biomarkers associated with treatment resistance. Recent innovations like Abbott Laboratories' Lingo, a bio wearable for continuous health tracking, and OncoDNA's OncoDEEP kit, enabling comprehensive biomarker testing and analysis, further underscore the dynamic evolution of technology in oncology. These advancements underline the crucial role of technology in shaping precise and individualized cancer treatments, necessitating equally tailored marketing strategies (Data Bridge Market Research), **[12].** Biomarker tests, guided by molecular characteristics, empower oncologists for precise treatment decisions, improving response rates and durations. 3. SWOT Analysis

Based on the above PESTEL analysis, a SWOT of the DCoMEX-BIO Project is presented.

Strengths:

1. **Innovative Technology:** DCoMEX-BIO employs cutting-edge predictive simulation and deep learning to create optimal biomarkers, offering a unique approach to predict and monitor tumor responses.
2. **Personalized Therapy Decisions:** DCoMEX-BIO software integrated with pre and post processing tools, provides clinicians with a commercial tool for personalized therapy decisions based on responders and non-responders.
3. **Market Growth Potential:** The increasing push for innovation and collaboration in the political landscape creates opportunities for DCoMEX-BIO growth, especially with a focus on personalized medicine.
4. **Mature infrastructure:** The current health care infrastructure is capable to adopt the new technology

Weaknesses:

1. **Regulatory Challenges:** Inadequate regulatory frameworks for complex biomarker-based diagnostic tests hinder DCoMEX-BIO development and integration into healthcare settings.
2. **Lack of Standards:** Current regulatory systems lack clear standards for evaluating new digital diagnostic tools, impacting their adoption and market entry.
3. **Costly Biomarker Quest:** The expensive quest for new biomarkers poses a financial challenge, impacting the project's efficiency and market penetration.

Opportunities:

1. **Political Support for Innovation:** Political factors support innovation and collaboration, shaping the market prospects for DCoMEX-BIO and emphasizing the need for adaptable regulatory procedures.
2. **Financial Support**: Financial support by individual member states and from the EU, such as Horizon Europe's backing for EIC Work Programme 2023, aids in developing novel biomarker-based assays.
3. **Collaborative Initiatives**: Initiatives to amalgamate scattered cancer imaging datasets foster predictive simulation and AI-based tools, highlighting the importance of collaborative efforts and data accessibility.

Threats:

1. **Privacy Concerns:** Prevailing social factors, such as privacy concerns regarding genetic and biomarker tests, can influence trust and acceptance among users, impacting market penetration.
2. **Integration Challenges:** Successful adoption depends on seamless integration into physicians' routines, requiring efforts to align DCoMEX-BIO with existing clinical practices.
3. **Economic Intricacies:** Economic factors, including industrial challenges and the unregulated diagnostic imaging sector, may pose challenges, emphasizing the need for cost-effective and innovative solutions.

In conclusion, DCOMEX-BIO exhibits strengths with opportunities in political and financial support, but faces challenges in regulatory and economic landscapes. Addressing weaknesses and threats through collaboration, improved regulatory frameworks, and innovative solutions is crucial for successful market entry and penetration.

3. Market Overview

3.1 Artificial Intelligence (AI) In Oncology

According to Precedence Research **[13]**, in 2022, the global market size for AI in oncology was valued at USD 890 million. Projections indicate a substantial increase to approximately USD 10 billion by 2032, demonstrating a remarkable CAGR of **28,18%** from 2023 to 2032. AI finds applications in cancer treatment, imaging, screening, and medication, with **cancer imaging** standing out as the most pioneering among these domains. AI aids in discovering anticancer drugs, predicting their mechanisms of action, and addressing resistance issues. In 2022, the **software solution** segment dominated the market with a revenue share of approximately 44%. This growth was attributed to an increasing number of market players offering software solutions tailored for oncology patients, focusing on follow-up care and treatment. The software enhances efficiency, streamlines workflow, and saves time. Various applications within the software domain, including **diagnostic imaging**, interventional radiology, and radiation oncology, are expected to fuel segment growth. Moreover, **the service sector** is projected to experience the highest growth due to the emergence of innovative startups providing advanced cancer treatment and predictive solutions, such as Concr's software service utilizing machine learning to predict cancer progression accurately in response to therapy.

In 2022, **chemotherapy** held the largest share in the treatment segment, accounting for 36,2%. It is a widely used cancer treatment method, with approximately 60% of Stage 4 prostate cancer patients undergoing chemotherapy, as estimated by the American Cancer Society. AI aids in customizing chemotherapy doses for individual patients by creating a digital profile, as seen in the successful application of CURATE.AI at institutions like the National University of Singapore and the National University Cancer Institute, Singapore (NCIS).

Immunotherapy is projected to have the **fastest growth rate of 39% during the forecast period**. This growth is attributed to an increasing number of FDA approvals and extensive clinical studies proving the effectiveness of immunotherapy. AI further enhances the precision of this therapy by identifying complex histocompatibility patterns associated with immunotherapy response by 91,66%, and is expected to drive its adoption in this segment.
In 2022, the hospital segment dominated the market, accounting for over 55% of the share. The increasing integration of AI solutions in clinics, addressing healthcare staff shortages and speeding up cancer diagnoses, is driving market growth. For instance, Addenbrooke's Hospital in the UK implemented InnerEye, a Microsoft Research Cambridge-developed deep learning tool, which aids in precise tumor identification, reducing CT processing time and treatment planning by up to 90%. Diagnostic centers are expected to exhibit the fastest CAGR from 2023 to 2032 due to increased **government funding and healthcare initiatives**. This growth is facilitated by well-trained specialized staff, advanced equipment, and medical expertise.
North America led the market in 2022 with over 55% market share, driven by the increasing incidence of cancer and access to advanced healthcare facilities. Additionally, the region's governments have significantly raised healthcare spending, with the United States witnessing an increase of 9,7% to USD 4,1 trillion in 2020. Presence of major companies like Pfizer and Roche in the region is expected to further expand the market. Key Market Players are: IBM, Azra AI, Siemens Healthineers, GE Healthcare, Intel, Path AI, NVIDIA, Concert.AI, Digital Diagnostics Inc., and Median Technologies.

According to PrecedenceResearch **[14].** The **global market size for cancer diagnostics** was assessed at **USD 132 billion in 2022** and is projected to reach about USD 305,39 billion by 2032, with an expected annual growth rate of 8,8% from 2023 to 2032. The increasing population of individuals diagnosed with cancer globally stands out as a significant catalyst propelling the expansion of the cancer diagnostics market.

The **global diagnostic imaging market according to PrecedenceResearch [15] was valued at US$ 28.12 billion** in 2022 and is projected to reach US$ 51,55 billion by 2032, exhibiting a notable CAGR of 6,3% from 2023 to 2032. Increased awareness among the public about advanced diagnostic tools and augmented healthcare spending are fueling the adoption of diagnostic imaging worldwide.

Ultrasound devices represented approximately 30% of the market share in 2022 due to their widespread use in healthcare. Factors contributing to their dominance include their cost-effectiveness, immediate and precise results, safety, radiation-free imaging, and non-invasiveness.
Conversely, computed tomography (CT) is expected to be the most promising segment during the forecast period. The surge in CT usage in 2022, particularly for diagnosing COVID-19 patients, led to its robust growth. Anticipated further advancements in high-precision CT scanners, incorporating technologies like artificial intelligence, are likely to propel this segment's expansion.

In 2022, **the oncology segment** led the global diagnostic imaging market in revenue and is expected to maintain its dominance. This is due to the increasing prevalence of cancer worldwide, notably lung and breast cancers, which have seen a significant rise in diagnoses and deaths.

Hospitals represented the largest share, over 45%, in 2022 among end users. The widespread presence of both public and private hospitals globally contributed to this segment's growth. Additionally, investments in technologically advanced hospital facilities equipped with sophisticated diagnostic imaging tools are expected to further boost this segment. Ambulatory imaging centers are anticipated to be a promising segment, primarily driven by investments aiming to expand these services into rural areas, providing advanced care in underdeveloped regions. Key players in the global diagnostic imaging market include GE Healthcare, Philips Healthcare, Hitachi Medical Corporation, Hologic, Inc., Siemens Healthcare, Samsung Medison, Shimadzu Corporation, Toshiba Medical Systems Corporation, Esaote S.P.A, and Fujifilm Corporation.

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3.2 Market Overview Summary

In summary, the DCoMEX-BIO, stands at the intersection of the dynamic global markets for digitalization and AI in oncology and medical imaging. Integrating the findings related to these markets, the DCoMEX-BIO is positioned amid significant trends and opportunities.

The global markets for AI in oncology and medical imaging are experiencing substantial growth of circa CAGR 28.18%. DCoMEX-BIO integration with these trends positions it as a key player in the evolving landscape of cancer diagnostics and treatment. DCoMEX-BIO role in predicting and monitoring tumor responses aligns with the increasing prominence of AI in oncology. The growing market size, dominance of software solutions, and advancements in cancer treatments, especially immunotherapy, provide a conducive environment for DCoMEX-BIO adoption. DCoMEX-BIO integration with diagnostic imaging aligns with the global diagnostic imaging market's growth. The project benefits from the increasing adoption of advanced imaging technologies.

While North America leads in market share, DCOMEX-BIO potential adoption in Europe, presents opportunities for market penetration. The alignment with prevalent cancers and the existing healthcare infrastructure in EU regions like Greece and Cyprus creates opportunities for DCOMEX-BIO integration.

4. Next Steps Strategy

As stated in the introduction, DCOMEX-BIO strategic roadmap encompasses various key facets crucial for its evolution from a project to a startup, as presented below: **Research Project/Grant for TRL Advancement:** The next critical step in DCOMEX evolution involves undertaking a new research project funded by a grant, and aiming to increase the Technology Readiness Level (TRL) and initiate *in silico* clinical trials. This grant will provide the necessary financial support to advance the technology and gather crucial data that will contribute to DCOMEX-BIO development.

Minimum Viable Product (MVP) Establishment (2025-2033): The initiation of a startup stands as the foundational step, with DCIOMEX-BIO focusing on refining its revolutionary technology to make a localized impact. Collaborative efforts with EU healthcare institutions, oncology centers, and diagnostic facilities are vital, as they form the backdrop for conducting experimental trials. The objective is to validate DCOMEX-BIO technology in a real-world setting. This phase is not only about technological refinement but also about establishing strategic partnerships with key stakeholders, including government bodies, medical professionals, and research institutions.

Technology Refinement and Validation: The empirical data gathered from experimental trials plays a pivotal role in refining DCOMEX-BIO technology. Real-world feedback becomes the cornerstone, ensuring the alignment of the technology with local healthcare needs and regulatory requirements. Seeking endorsements and certifications from relevant healthcare authorities in EU countries is a crucial step, solidifying DCOMEX-BIO credibility in the healthcare landscape.

Market Penetration in Greece: A comprehensive marketing strategy takes center stage, aiming to create awareness about DCoMEX-BIO capabilities among local healthcare professionals. Offering the **technology as a service** to oncologists and radiologists becomes a key focal point, emphasizing its effectiveness in predicting and monitoring tumour responses. Positioning the MVP as a cost-effective solution addresses the budget constraints prevalent in the local healthcare system, making DCoMEX an attractive proposition.

Strategic Partnerships: Forge alliances with leading healthcare institutions, oncology centers, and diagnostic facilities in EU. The goal is to seamlessly integrate DCoMEX-BIO into existing workflows and protocols, ensuring its adoption becomes an integral part of the healthcare ecosystem. Collaboration with research organizations and universities remains ongoing to continuously refine the technology and contribute to scientific advancements in the field.

Preparation for EU Market Expansion (2028 Onward): Leveraging success and insights gained from the Greek MVP, DCoMEX-BIO is poised to expand into the larger EU market post-2028. Seeking additional funding and strategic alliances becomes imperative for scaling operations and deploying the technology effectively. Aligning the technology with the specific needs and regulatory landscape of the EU healthcare market sets the stage for a successful expansion.

Global Licensing Strategy: DCOMEX-BIO prioritizes safeguarding its intellectual property by patenting the technology. The strategic positioning of DCOMEX-BIO as an attractive investment for technological global companies underscores its potential in the highly competitive fields of oncology and diagnostic imaging.

Attraction of Technological Global Companies (Samsung Medision, Koninklijke Philips N.V., Siemens Healthineers, Hitachi Ltd and others): The development of a compelling value proposition becomes essential, highlighting DCOMEX-BIO unique features, efficacy, and transformative impact on the global healthcare landscape. Targeted marketing campaigns, outreach initiatives, participation in industry conferences, and collaborations with key opinion leaders collectively enhance visibility, capturing the attention of technological global companies.

License Sales and Revenue Generation: Negotiating licensing agreements with global companies becomes a key milestone, emphasizing DCOMEX-BIO exclusivity and competitive advantage. Structuring deals that provide a sustainable revenue stream ensures financial viability and growth, paving the way for DCOMEX-BIO to become a major player in the global healthcare technology arena.

5. Conclusion

The comprehensive assessment through a detailed market research provided invaluable insights into crucial aspects of DCoMEX-BIO adoption within the healthcare sector. The tool's predictive capabilities align with the rising demand for personalized therapy decisions, providing a comprehensive solution for multiple prevalent cancer types. DCoMEX-BIO strategic roadmap outlines key objectives from establishing a Minimum Viable Product (MVP) in Greece to refining and validating technology, penetrating the local market, and preparing for expansion into EU. The global licensing strategy, targeting technological global companies, emphasizes

the need to safeguard intellectual property, while the focus on revenue generation through licensing deals ensures long-term financial viability. In conclusion, DCOMEX-BIO strategic roadmap, position it as a key player in advancing oncology technology solutions. The positive adoption trends, competitive pricing, and market-specific strategies align with the unique dynamics of EU markets, setting the stage for DCOMEX-BIO to make a significant impact in the global healthcare technology landscape.

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