



BGM Associates Working Paper

Global Medical Diagnostics 2030
A Quantitative Perspective

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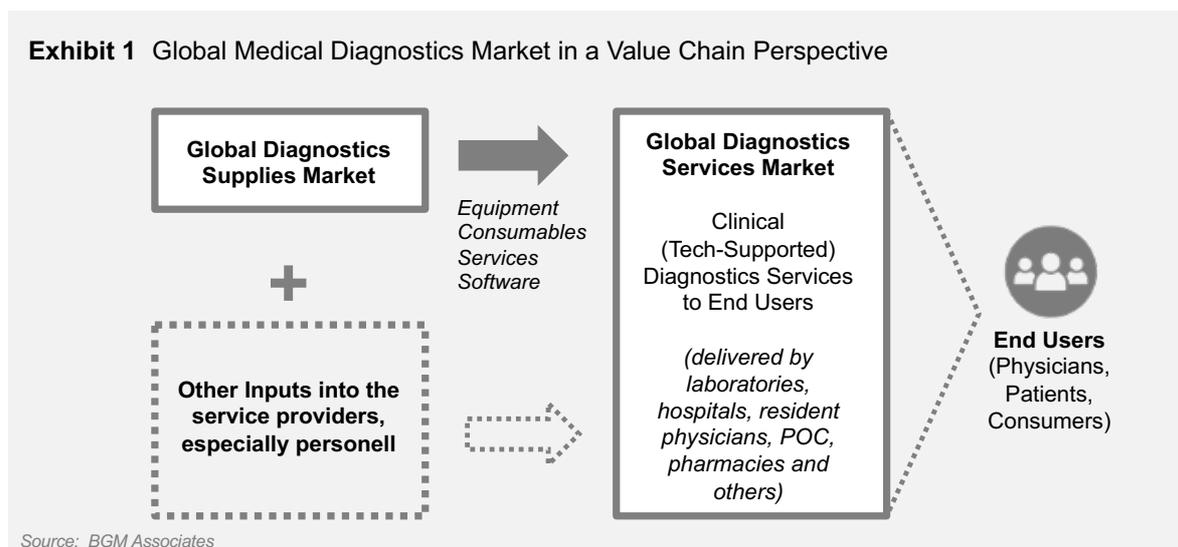
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1. A Comprehensive Perspective on Medical Diagnostics

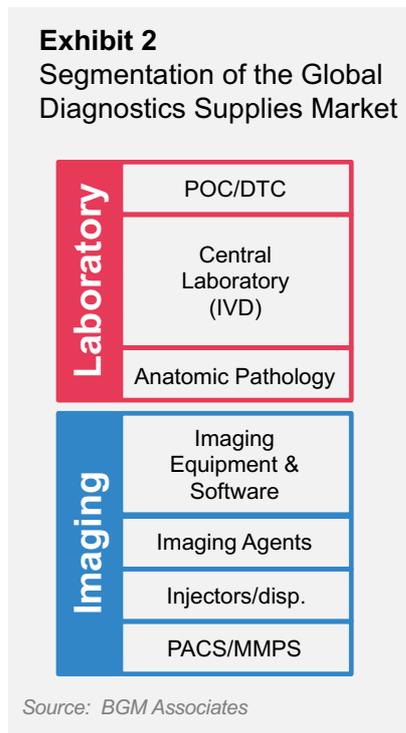
One focus area in BGM Associates' consultancy practice is the field of medical diagnostics and its associated supplier industries. In this context, as part of our ongoing work, we review the broader long-term developments in this field from time to time in order to assess on a high level the attractiveness and commercial viability of the medical diagnostics industry at large. In this paper, we focus on a **quantitative** outlook on the sizes and dynamics of medical diagnostics markets for the next decade until 2030. While we are highly interested in new technologies, the role of artificial intelligence (AI) in diagnostics, and medical innovation we touch upon such topics only briefly and mainly with the perspective of whether they have the potential to be translated on a broad scale into daily medical practice with a significant market impact in the next decade.

While most market reports focus on either diagnostic devices, instruments and supplies or medical clinical services, it is our aim to put these two principal stages of the value chain in perspective. On a more general level, we provide a very broad global expenditure estimate of the **'Medical Diagnostic Services Market'**, i.e., the actual services provided to patients or amongst providers by laboratories, pharmacies, hospitals, radiology centres, etc. At a more detailed level, we then look upstream into the **'Diagnostic (Industrial) Supplies Market'**, which provides input such as instruments/equipment, services, consumables, and software to the service providers (Exhibit 1).



We divide the diagnostic supplier markets into two large 'macrosegments': 'Laboratory' ('Ex vivo') and Diagnostic Imaging ('In vivo') (see appendix for definitions). The **Laboratory Supplier Macrosegment** comprises in our definition Point-of-Care and Direct-to-Consumer

IVD testing supplies (POCT/DTCT), the large segment of Central Lab IVD testing, and tissue-based Pathology Diagnostics (including both conventional Anatomic and Digital Pathology).



The **Diagnostic Imaging Macrosegment** is divided into Imaging Equipment and related Software/Services, Imaging Agents, Injectors incl. disposables, and Medical Image Management and Processing Systems (MIMPS), formerly referred to as Picture Archiving and Communication System (PACS) Software.

Our market forecast projections are indicative, and we provide rather an informed speculation derived from a combination of outside sources coupled with our database and assumptions based on our deep industry expertise in the biopharma and medical-device industries and our extensive business and consulting experience, in particular in the medical diagnostics and imaging space (refer to the Appendix for some further explanations).

2. Drivers of Diagnostic Services Expenditure Growth

The global value expansion of medical diagnostic testing services and the diagnostic supplier markets in the decade to 2030 will be driven on the ‘**demand-side**’ by three megatrends:

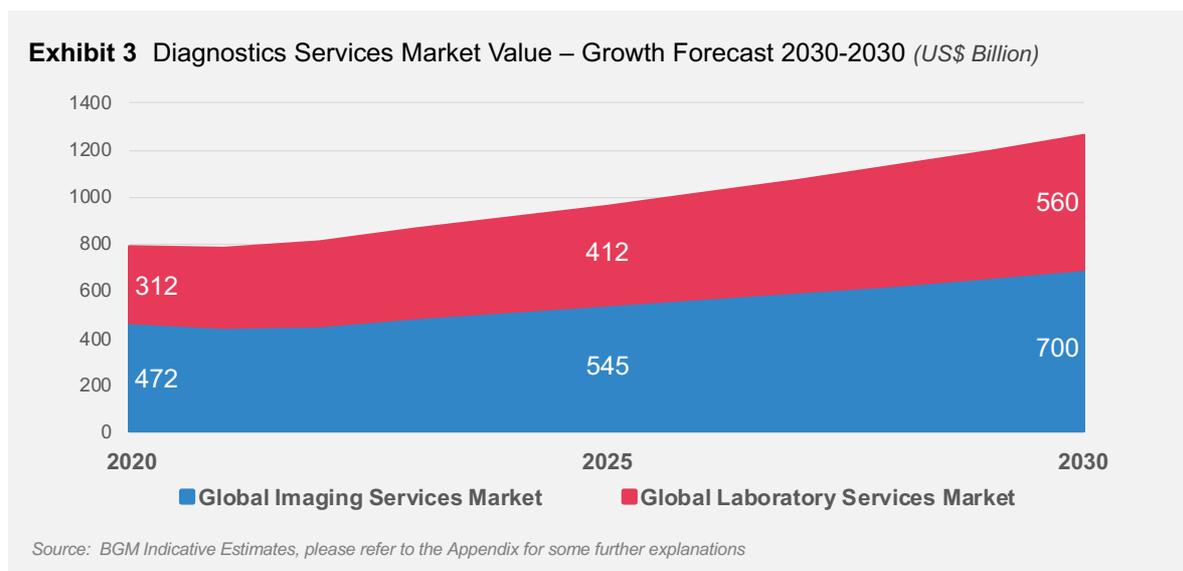
- **Access and Demography:** Between 2020 and 2030, a growing share of the world population will get first-time access* or access to more advanced diagnostic services (mainly in China). Moreover, the world population will grow by some 800-850 million people, mostly in Africa and the less developed regions of Asia.
- **Disease Incidence and Prevalence:** A further rise in the global disease burden will be fuelled by increases in chronic as well as non-communicable diseases, in infectious diseases and related pandemic risk provisions, and in ongoing environmental risks like air pollution, chemical pollution or food contamination, among others.

* According to the latest report of the Lancet Commission on diagnostics 47% of the global population has little or no access to diagnostics. Fleming et al (2021). The Lancet Commission on diagnostics: transforming access to diagnostics. Published Online on October 6, [https://doi.org/10.1016/S0140-6736\(21\)00673-5](https://doi.org/10.1016/S0140-6736(21)00673-5). We assume that the Covid 19 pandemic will give new impetus to the UN’s sustainable development goals concerning access to quality healthcare (and in this context especially to diagnostic coverage) leading to a (slow) decrease of this share in the next decade.

- **Therapy innovation:** Progress in therapies and the trend towards personalized medicine will increase the demand for related diagnostics services, especially at the level of molecular diagnostics/genetics, but also for instance in molecular imaging.

On the other hand, incremental as well as more disruptive innovation on the **supplier’s side** in diagnostic medical devices, software and related services drive investments in the renewal or expansion of existing infrastructures over the whole decade. However, while all these market drivers contribute to the dynamic expansion of medical diagnostics markets with many opportunities for diagnostics services providers and suppliers, growth is also **restrained** by regulatory measures, unfavourable reimbursement policies and restricted hospital budgets in many markets around the world.

Based on our research and considering the impact of Covid-19 our estimate of expenditures in 2020 for **total global Diagnostics Services** is in the order of close to US\$ 800 billion. Taking into account the megatrends and innovation drivers we project growth to some US\$ 1.3 trillion by 2030 (Exhibit 3). As a rough comparison and with many caveats **Diagnostics Services represent some 10% of total global healthcare expenditures** over the whole decade to 2030*. **Laboratory Diagnostic Services** in our definition and **Diagnostic Imaging Services** represent roughly one third and two thirds respectively of the expenditures for diagnostics services. The estimated sizes and trends result – as we shall see – in a significant overall demand growth in the supplier markets throughout the next decade and underpin their continued attractiveness from a business perspective.

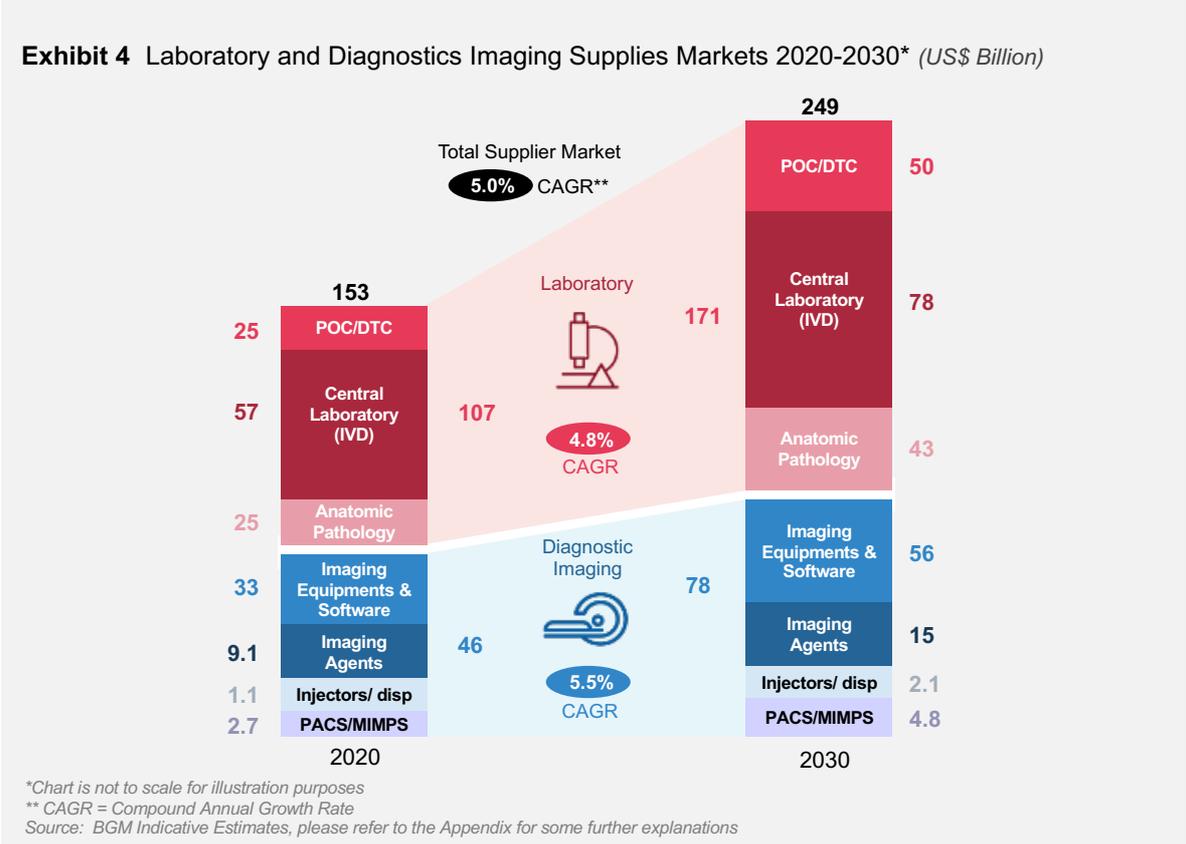


* The WHO estimates total global healthcare expenditure at US\$ 8.3 trillion for 2020 (World Health Organization (2020). Global spending on health 2020: weathering the storm. <https://apps.who.int/iris/handle/10665/337859>). Based on various sources we project around US\$ 13 trillion for 2030.

In the following section, we turn from the diagnostic **services level** to the quantitative trends in **supplies** markets where we will look into Laboratory Supplies Markets and Diagnostic Imaging Supplies markets, in turn.

3. Diagnostics Supplies Markets in the Next Decade

The total **Laboratory Supplies Macrosegment** with its three markets (POC/DTC, Central Labs, Anatomic Pathology) is estimated at around US\$ 107 billion in 2020 and will reach some US\$ 171 billion by 2030 (see for this and the following Exhibit 4). The **Diagnostic Imaging Supplies Macrosegment** with the four markets reflected in our analysis is less than half of the Laboratory markets with US\$ 46 billion in 2020 and will grow to some US\$ 78 billion in 2030.



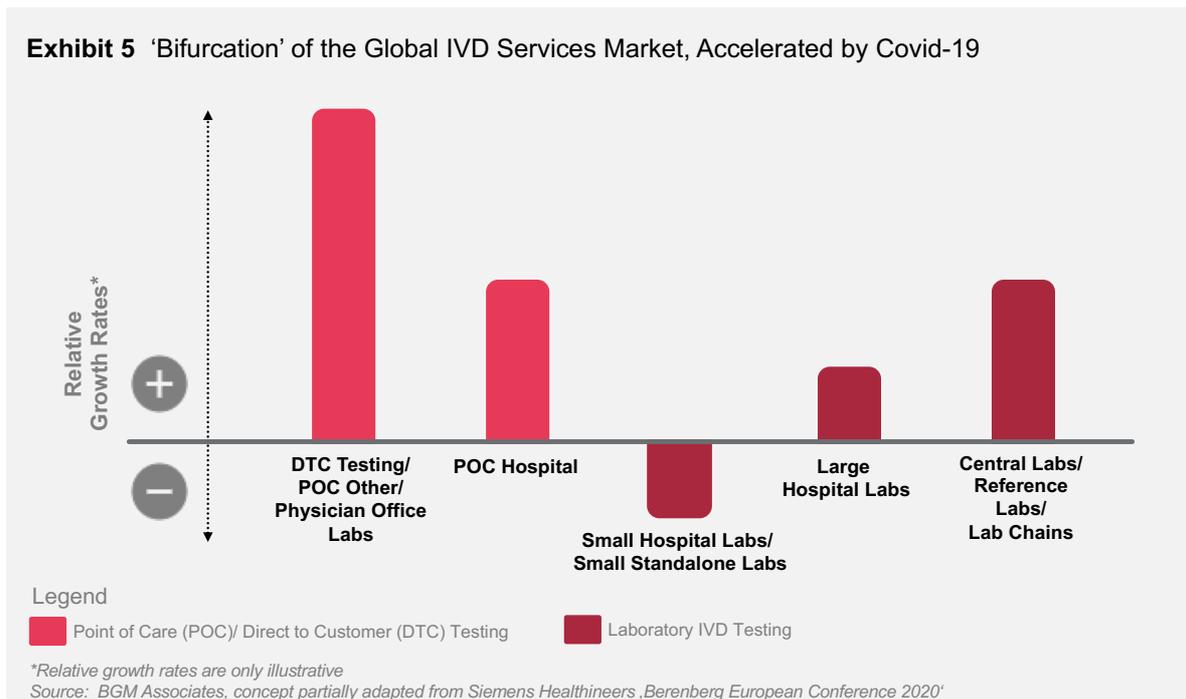
3.1 Laboratory Supplies Markets

Covid-19 led in 2020 to a sudden push (we estimate the 'Covid-19 effect' at around +3-4%) for the overall Laboratory Supplies Macrosegment in our definition, and we assume a gradual return to a pre-Covid-19 growth path until 2024 including the shift towards POC/DTC (see below).

POCT and Central Laboratory Supplies

The most relevant lasting impact of Covid-19 in overall quantitative terms is in the long-term **acceleration of demand for POC/DTC testing supplies**. The POC/DTC supplies market exhibited fast growth already before Covid-19 inter alia because of the increasing **clinical integration** of diagnostics at the POC. However, the pandemic has increased the **awareness** of hundreds of millions of people worldwide of the need and benefits of diagnostics in general and POC/DTC in particular¹. According to our estimate, this ‘coming of age’ of POC and DTC testing will lead to a more than doubling of the POC/DTC supplies market from US\$ 25 to some US\$ 50 billion in 2030.

The ‘**decentralization**’* of lab testing to the POC or the home on the one hand is accompanied by an ongoing **centralization** of lab testing in larger central labs implying a ‘**bifurcation**’ of the market (see exhibit 5). One important ongoing trend in central laboratories is automation under the Banner of ‘**Total Laboratory Automation**’(TLA).² The integration of various analyzers and connected assembly lines and the software-enabled



management of all pre-and postanalytical steps in one system is currently being implemented in ‘hub laboratories’ in the US and other countries. By the end of the decade, we believe that this ‘**industrialization**’ of central lab testing will be completed in the

* The decentralization of testing to the POC and the home is one element in a much broader digitally enabled decentralization of healthcare delivery. See for instance Chiang (2020). Back to the future: Digital health-led decentralization of healthcare delivery. MobiHealthNews, July 24, mobilhealthnews.com; Jayamani et al (2020). Decentralisation of healthcare system due to Covid-19 and its impact on hospital-based laboratories-pandemic panic patients’ reflection? Journal of Responsible Technology, Oct; Volume 1: 100003

advanced countries. TLA then will also become the primary field of the application of AI in the context of cyber-physical systems and ‘automation 4.0.’³

While we assume an overall **moderate growth** of the Central Laboratory Supply market in the next decade (from US\$ 57 to US\$ 78 billion in 2030), **Molecular Diagnostics** has been an exceptionally dynamic field even before Covid-19 has turned an additional spotlight on this segment. With capacities for Polymerase Chain Reaction (PCR) dramatically expanded because of the pandemic, cancer, infectious and rare diseases as ongoing major drivers, the growing role of companion diagnostics and the progress in Next Generation Sequencing (NGS) this segment will grow with (low) double digit growth rates until 2030. In view of major hurdles like the evolving regulatory landscape, the complex methodologies and demanding protocols, the issues of standards in data interpretation and the shortage of qualified personnel it remains to be seen to what extent NGS will find its way into clinical routine globally in a major way. Finally, another potentially disruptive approach in molecular diagnostics to improve the speed, sensitivity, and specificity of diagnostic tests, CRISPR (clustered regularly interspaced short palindromic repeats)-CAS systems especially for POC in low resource settings is on the horizon and may get traction over the decade.⁴

Anatomic Pathology Diagnostics Supplies

The third segment of the Laboratory Supplies macrosegment – Anatomic Pathology diagnostics – has been hit negatively by Covid-19 in 2020 but is nevertheless expected to grow in the longer perspective from US\$ 25 billion in 2020 to US\$ 43 billion in 2030. Apart from growth in increased access in emerging economies, a long-term driver is the increase in cancer prevalence and better cancer treatments which raise the need for long-term chronic care with concomitant diagnostics. Pathological analysis of biopsied tissue is and will remain the gold standard of cancer diagnostics and other diseases in the foreseeable future, but the pressure to modernize, solve its ‘under-automation’ (in view of the global shortage of trained anatomical pathologists), and to better integrate into the diagnostic pathway, will increase further in the next decade⁵. One partial solution and growth driver in this segment is the subsegment of **Digital Pathology**, which we expect to triple in the decade, albeit from a low base of US\$ 0.7 billion to US\$ 2 billion. ‘Virtual microscopy’ in tissue-based pathology diagnostics is based on digitized specimen slides which facilitate the management, (remote) sharing and computer-assisted interpretation. We do expect this shift to improve the quality, consistency, and efficiency in this diagnostic branch, among others by applying AI-based image interpretation techniques.⁶

3.2 Diagnostic Imaging Supplies Market

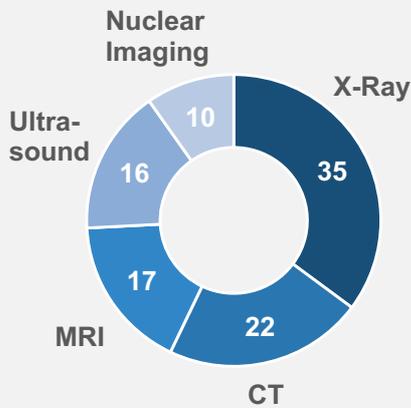
From the discovery of X-Rays more than 120 years ago through the introduction of Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) in the 1970s, of modern contrast agents and nuclear diagnostic systems until today diagnostic imaging has been a field of disruptive as well as continuous incremental innovation. Advances in diagnostic imaging in practically all modalities have been at the forefront of progress in medical diagnosis in the last decades, now more and more driven forward by progress in digitization, storage, analytics and AI.

We project the **overall diagnostic imaging supply macrosegment** to grow – taking into account a small Covid-19-related dip in our base year 2020 - from US\$ 46 billion to US\$ 78 billion in 2030 (see Exhibit 4). In our definition, the diagnostic imaging macrosegment consists of four supplier markets: imaging equipment & related software, imaging (contrast) agents, injectors, and PACS/MMPS software.

Imaging Equipment & Software

More than one third of the total imaging equipment & software market in the order of US\$ 11 billion represents the broad variety of **X-Ray devices** including mammography equipment, followed by **CT equipment** with some US\$ 7 billion or 22% in 2020 (see also Exhibit 6). Innovation in both markets is driven by the quest for higher quality images, shorter acquisition times, and also the **reduction of radiation exposure**. A specific driver in the X-Ray segment is the increasing use of **interventional** X-ray systems including innovative C-arms. Breakthrough technologies like photon counting CT (the first CT scanner of this kind was FDA approved in September 2021)⁷ will gain traction in the next ten years but will remain a (high end) niche until the end of the decade.

Exhibit 6
Segment Shares in Diagnostic Imaging Equipment & Software Market Value 2020 (in %)



Source: BGM Indicative Estimates

While X-Ray, CT and Ultrasound are broadly accessible and access **and** innovation drive demand growth, **MRI** - although being the gold standard of imaging diagnostics in many medical indications - is still constrained by complexity, high cost and demanding infrastructural conditions. In this market which is estimated at US\$ 5.4 billion for 2020 technical innovation is however progressing fast and will increase the outreach and clinical useability of MRI over the decade. Among others, **two opposing trends** will shape the next decade: a trend to higher end scanners (e.g., replacement of 1.5 Tesla scanners by 3T scanners) on the one end, and a growing availability and use of cheaper, lighter lower field strengths scanners supported by rapid progress in

post-processing technologies on the other.⁸ This may help to mitigate to some extent the current extreme differences in MRI units per capita among advanced countries and between them and less developed countries.*

As a real-time, non-invasive and radiation-free method at comparatively low-cost **Ultrasound** has narrowed the gap to X-Ray, CT and MRI through many disruptive innovations over the last decades. With US\$ 5.3 billion the Ultrasound equipment & software market is only the fourth largest segment, but **in ultrasound we will likely see the most dynamic development over the next decade** (despite a short-term decline in 2020 due to Covid-19). Many existing innovations will still have to make their way into broad clinical use (e.g., contrast-enhanced ultrasound); moreover, a multitude of ongoing and coming innovations will make Ultrasound more ubiquitous at the POC⁹, more automated, more definitive and intuitive for users so that one review denoted it even as the '60-year-old modality of the future¹⁰. **Nuclear imaging** (NI) by means of Single-Photon Emission Computed Tomography (**SPECT**) and Positron Emission Tomography (**PET**) scanners is an area that underwent profound changes over the last decades and has affected how oncology, cardiology and neurology patients are diagnosed and treated¹¹. With a total segment value of US\$ 3.1 billion in 2020 NI has a solid basis that will definitely grow in

* Per million population Japan, the US and Germany count 55, 40 and 35 MRI scanners while France, Belgium and Hungary have 15, 12 and 5. For many developing countries the number is below 1. See for OECD countries: OECD iLibrary. Health at a Glance 2019: OECD Indicators. <https://doi.org/10.1787/888934017690>. For developing countries see WHO, Global Health Observatory data repository. Medical equipment by country. <https://apps.who.int/gho/data/node.main.510> (accessed 07 October-2021).

importance in the coming decade alongside the advancement of hybrid scanner technologies combining PET with CT and MRI and whole-body scanning capabilities.¹²

Imaging Agents, Injectors, and PACS/MIMPS

We project the **global imaging contrast agent supplier market** to grow from US\$ 9 billion in 2020 to US\$ 15 billion in 2030, with the expectation that the established compounds such as iodine-based contrast agents for X-Ray and CT and gadolinium-based contrast agents for MRI are here to stay in the forecast period. Growth in this space will be driven mainly by increased access to contrast-enhanced modalities and techniques in emerging economies, as well as expansion of indications. The ongoing developments of organ-specific contrast agents are promising even though it is expected to only affect the market dynamics of certain niche areas. The **injector and disposables market** is expected to follow closely with the imaging contrast agent market, with stable growth from US\$ 1 billion in 2020 to US\$ 2 billion in 2030. The **MIMPS market**, previously PACS, is expected to closely follow the imaging equipment systems market with growth from US\$ 2.7 billion in 2020 to US 4.8 billion in 2030.

4. Concluding Remarks

In the next decade, driven by four global ‘**mega-trends**’ (access/demography, disease burden, therapy innovation, and significant innovations by suppliers) the global diagnostics services markets and consequently the global demand for diagnostics **equipment & supplies** will grow steadily (in our estimate with a CAGR of over 5%). In terms of **innovation**, the US remains in the lead with other advanced Asian (Japan, South Korea) and European countries following closely. If we look at the combination of **disease burden** and widening **access** China will remain the single most important ‘driver country’ in the next decade.

The growth prospects for the diverse groups of supplier companies which participate in these markets* are generally good provided they can keep up with the innovation-driven competition in their domains – a condition which eventually favours further industry consolidation in the next decade and increases entry barriers for new players. A potential

* We did not look in this paper into the structure of the supplier companies in the various markets. While generally laboratory equipment and supplies markets and diagnostic imaging equipment and supplies markets are served by different sets of companies (e.g., Roche Diagnostics or Abbott Healthcare on the one hand or GE Healthcare and Philips on the other) there are a few companies which combine activities in both markets in one company (e.g., Siemens Healthineers). Contrast agents are provided by pharma companies like Bayer or Bracco, injector makers are smaller standalone companies or part of contrast agent companies. While the mentioned markets are served by global players the MIMMS supplier market is still fragmented and often dominated by local companies from the respective regions.

new group of major industry players comes from China in the field of diagnostic imaging equipment. However, despite the impressive progress of some of these new ‘challengers’ (like Neusoft or United Imaging Healthcare) we do not believe that they will gain a significant share in advanced economies in the next decade.

Potential transformational trends

Going beyond the quantitative and industry perspective and the specifics in the various markets we would like to briefly address three broader potentially transformational innovation trends (in medical diagnostics) in the next decade and beyond: AI and Machine Learning (ML) in diagnostic imaging, ‘Integrated Diagnostics’, and the ‘empowered patient’.

In the coming decade diagnostic imaging is doubtless one of the if not **the** most promising arena(s) of **AI/ML application in diagnostics** in particular and even in healthcare at large. Diagnostic imaging is naturally suited as it is completely digitized and works with tech-affine personnel (radiologists, radiographers or cardiologists for example) who are in short supply and under heavy work pressure due to an ever increasing (even ‘exploding’) amount of imaging scans from more performant scanners and expanding use. There are now several hundred AI/ML applications with a wide variety of use cases (e.g., helping to detect lesions, taking on tedious tasks like segmenting structures and helping triage case criticality) which can however be divided into two basic types: AI to improve workflows and AI for clinical decision support. In the US the Federal Drug Administration (FDA) has approved to date some 350 AI applications¹³ of which around 130 are imaging-related, and the first reimbursements for AI tools were introduced.¹⁴ However, there are still major barriers to a broader penetration of AI in diagnostic imaging such as the full integration into clinical workflows including MIMPS/PACS, the applicability across different technical, divisional and institutional settings, and the sheer number of competing vendors as well as the complexity of products they provide.

While there is universal agreement that AI will significantly change diagnostic imaging in the long term, many observers see AI/ML in diagnostic imaging still in its ‘infancy’. Therefore, while we will see a broader application for selected use cases (especially in the workflow area and in image acquisition or processing) in the next 3-5 years the full penetration and transformational impact in terms of clinical decision support will only play out in the second half of the next decade.

Medical diagnostics is today still largely carried out in ‘silos’ -radiology, laboratory diagnostics, and pathology are conceptually and institutionally separated diagnostic disciplines. At the same time, it is undisputed that **‘Integrated Diagnostics’** (within the professionalized healthcare space) which can be defined as ‘convergence of imaging, pathology and laboratory tests with advanced information technology (...) has the potential for revolutionizing the diagnosis and therapeutic management of diseases including those that cause the highest number of worldwide deaths (i.e., cardiovascular disease, cancer, and infectious diseases)’.¹⁵ While ‘Integrated Diagnostics’ is already today practised for instance in the form of multidisciplinary tumour boards or case conferences there are significant IT infrastructural as well as interdisciplinary **barriers** to the combination of bioinformatics and imaging informatics as well as to the sharing across healthcare providers, and consequently to the application of intelligent data analysis techniques across silos. As we believe that the speed of translation of innovation into medical practice is usually vastly overestimated and the regulatory, institutional and technical barriers are regularly underestimated a broader and effective ‘Integrated Diagnostics’ may - apart from isolated ‘islands’ and ‘niches’ - have to wait for a time beyond 2030.

As a final thought, we would like to briefly touch upon the topic of the **‘empowered patient’** or consumer who monitors her/his health **real-time with wearables and other devices** and/or conducts tech-enabled home testing for various conditions.* The ‘explosion’ of fast mobile-based diagnostic technologies has led to optimistic visions for healthcare in general and diagnostics in particular for the next decade and beyond.** While wearables or other devices facilitate real-time or frequent self-testing of certain chronically ill patients already today (e.g., glucose testing in diabetes) the potential of consumer devices to **broadly prevent diseases** or **intercept them early** will depend on whether and how fast their big tech promoters like Apple et al can ‘circumvent’ or overcome the many challenges ahead. Among them are the built-in resistance to change (“inertia”) of our current healthcare systems, the limited ‘medical literacy’ in the general population, the insufficient state of and access to Electronic Medical Records, and regulatory, privacy and security issues. While we believe that we will see a fundamental

* The devices include watches, activity trackers, clothing, contact lenses, rings, embedded sensors, ingestible devices or everyday use facilities like toilets.

** E.g., “By 2030, healthcare will be centred on patients empowered to prevent diseases rather than seek treatment. (...) all of this will be enabled by data and algorithms and provided within a healthcare system that is organized and regulated in an entirely new way”. Strategy&/PwC 2019. Driving the Future of Health. PDF Online. Or: “...streams of health data—together with data from a variety of other relevant sources—will merge to create a multifaceted and highly personalized picture of every consumer’s well-being” Deloitte (2021). Forces of change – the future of health. PDF online

transformation of healthcare and diagnostics in the future which may include a more 'empowered patient', the next decade will be more of a 'gestation period' for a fundamental transformation which will extend into the middle of the century.

Appendix: Some methodological explanations and remarks

The two major diagnostic ‘macrosegments’ are in our definition ‘**Laboratory Diagnostics**’ and ‘**Diagnostic Imaging**’ (or Medical Imaging).

- (Medical) ‘**Laboratory Diagnostics**’ comprises of In Vitro Diagnostic Testing (IVDT) and tissue-based Pathology Diagnostics. We distinguish for IVDT principally lab-based In vitro diagnostic tests and Point-of-Care/Direct-to-Consumer (POC/DTC) tests. **Lab-based IVD tests** are non-invasive tests performed in a laboratory setting (e.g., hospital labs, standalone labs, central labs, specialized labs) on biological samples (for example blood, urine or tissues) to diagnose or exclude a disease. **POC** comprises all tests that are performed at or near the point of patient care instead of sending samples to a laboratory. **DTC** refer to medical tests performed at home with or without involving a doctor’s prescription or other healthcare professionals.
- We segment the field of **Pathology Diagnostics** into Anatomic and Digital Pathology. **Anatomic pathology** studies the effect of disease on the structure of body organs. It primarily consists of tissue evaluation and interpretation of individual cells from a pap smear, a needle aspiration of a mass. We define ‘**Digital Pathology**’ as a sub-field of Anatomic pathology that uses ‘virtual microscopy’ based on digitized specimen slides.
- **Molecular diagnostics** applies molecular biology to medical testing. It comprises a collection of biological markers (that are signs of a normal or abnormal process, or of a condition or disease) in the human genome or proteome.
- **Diagnostics Imaging** (DI) comprises all procedures that use instruments, disposables, contrast agents and software to view the interior of the human body to diagnose the state of health and disease. We have included Interventional Radiology (various minimally invasive procedures which use medical imaging guidance) as far as feasible. We divide DI supplies into the following four markets.
- **Imaging Equipment & Software** includes equipment, related services, and the associated post-processing and image interpretation software: We consider the following modalities/markets: X-Ray including mammography and equipment for interventional imaging, Computed Tomography (CT) which also uses X-rays, Magnetic Resonance Imaging (MRI), and Nuclear Imaging (Single-Photon Emission Computed Tomography (SPECT), Positron Emission Tomography (PET) and hybrid technologies in combination with MR or CT Scanners. Moreover, we included C-arms (fluoroscopy machines), which get its name from a C-shaped arm and are mainly used for intraoperative imaging in a wide range of interventional minimally invasive procedures for instance in image-guided biopsies or coronary angioplasty with stenting.
- **Imaging Agents** refer to injectable contrast media that absorb or alter electromagnetism or ultrasound, or to radiopharmaceuticals that emit radiation.
- Contrast Agent **Injectors and Disposables** are used to inject contrast media or contrast agents to enhance the blood and perfusion in tissues for better image acquisition.
- **Picture Archiving Systems or Medical Image Management and Processing Systems (PACS/MIMPS)** are mainly data storage systems that include quantitative software functions.

We have constructed our data based on cross-referencing our existing BGM database and assumptions with a distilled selection of available market reports, statistics reports, and annual reports of leading supplier companies. Technical issues and trends are based on our industry expertise or are collected from articles, surveys, technical symposia and trade journals. Our market forecast projections are indicative, are predominantly our assumptions based on our deep industry expertise in the biopharma and medical-device industries and our extensive business and consulting experience in particular in the medical diagnostics and imaging space, coupled with a ‘plausibility check’ of various projections from simulation models in selected available reports.

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