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Thoughts on the Future of Medical Imaging
An Industry Perspective

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1 Introduction: Diagnostic imaging at a crossroads

The development of diagnostic imaging during the past 50 years is one of the greatest success-stories in the history of medicine and applied sciences at large. The incredible progress made in visualizing the anatomy and function of the human body and thus to empower medical doctors to exclude, detect, characterize and eventually treat diseases, has revolutionized medicine in the second half of the 20th century.

Medicine today is unthinkable without Computed Tomography, Magnetic Resonance Imaging, Ultrasound and more recently Positron Emission Tomography as well as combined hybrid-technologies such as PET-CT and PET-MRI and image fusion. This ranges from fetal ultrasound monitoring and early breast cancer screening to pre-operative planning of e.g. liver surgeries, to mention only a few applications.

Diagnostic imaging has become not only a key element of modern healthcare but also a prospering industry and employment sector with an overall market value of about EUR 32 bn. While the early beginnings of imaging partially originate in small and medium-sized companies, both the quest for economies of scale and competitive dynamics have created an industry that is – to a great extent – characterized by oligopolistic competition with large and dominant businesses among equipment manufacturers and pharmaceutical companies, complemented by specialized, often regional, niche players.

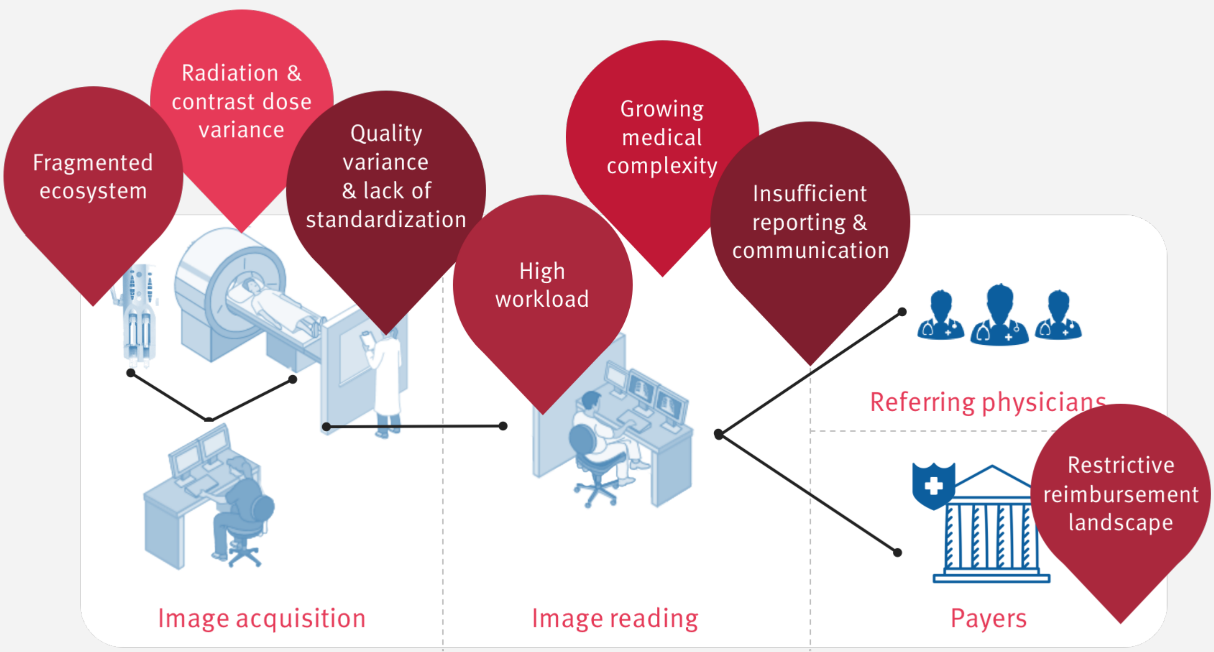
However, the imaging industry is at a crossroads and will profoundly change during the next decade with novel technologies and new players entering and redefining the competitive landscape. The incumbent equipment manufacturers face increasing competition from new entrants such as Samsung Electronics, Neusoft Medical Systems or Mindray Medical in emerging but also developed markets. The leading contrast media companies will see increasing generic competition as the remaining contrast agent patents expire within the next years. Likewise does the recent entry of IBM into radiology software through the acquisition of Merge Healthcare highlight the growing importance of software in radiology and diagnostics at large. These trends spur a wave of consolidation, which we already witness with Guerbet's acquisition of Mallinckrodt's contrast business and Toshiba's ongoing partnering process.

This paper summarizes our thoughts on the current shortcomings of radiology as well as on technological and business model innovations that will drive change and transformation in the coming decade. We discuss how these dynamics may influence the industry and how incumbents may respond to the competitive challenges ahead.

2 Shortcomings and challenges in the radiology practice

Despite the tremendous progress and the important role of radiology in the medical workflow, the discipline still faces a number of critical shortcomings and challenges, many of which can be found in different settings across the globe: (1) a fragmented ecosystem with outdated equipment, (2) variance in quality and lack of standardization, (3) variance in radiation and contrast dose exposition, (4) high workload of radiology personnel, (5) growing medical complexity, (6) insufficient reporting & communication with other disciplines, as well as (7) an increasingly restrictive reimbursement landscape.

Figure 1 Shortcomings and challenges in the radiology practice



Source: BGM Associates

(1) Fragmented ecosystem and outdated equipment

The radiology ecosystem – namely scanner, PACS workstation, image archive, contrast media and injectors – remains largely fragmented today: the devices do barely communicate with each other and are insufficiently geared to each other. For instance, radiology technicians in many hopitals still have to note contrast media injection parameters in a dedicated book, which is time consuming and makes follow-ups difficult and quality management impossible. A seamless integration of the ecosystem would greatly improve handling and workflow, but also allow for quality improvements. The potential synergies are no secret but all co-development initiatives remained insufficient to date, presumably for strategic reasons as well as liability concerns of involved companies. This issue is accentuated by the fact that there is a large number of outdated imaging systems installed, which produce insufficient image quality at too high doses and are difficult to integrate with other systems.

(2) Quality variance & lack of standardization

While nobody questions the achievements and the obvious value of radiology for diagnosis and treatment decisions, most physicians and radiological societies acknowledge that there is great variance in image quality and diagnostic accuracy across the discipline.[1] Both image acquisition and image interpretation highly depend on the individual equipment and operator experience and training. Hence, there is great potential for improvement through standardization. As a result of quality variance, the radiological discipline gets increasingly under pressure by payors and referring physicians. The 'Value Debate'[2] in the United States has put the topic onto the agenda and yields first positive results as large hospitals agree to define standardized protocols for all major imaging examinations.

(3) Radiation and contrast dose variance

Recent studies and shed more light on the large variance of both radiation and contrast media dose in CT imaging.[4] Despite the great achievements of radiation and contrast media dose reduction through modern imaging and injection equipment, individual imaging and injection protocols still cause risky overdosing in some CT exams.[5] California and Texas in the USA are forerunners by passing legislation that requires radiologists to track radiation safety metrics.[6] In the European Union, too, a directive based on EURATOM safety standards demands any medical equipment producing ionizing radiation installed after February 2018 to be capable of dose tracking.[7]

(4) High workload

Radiologists and technicians face an ever-growing workload due to the large number of imaging examinations as well as the quantity of images that needs to be read per study. This holds true across the globe and is accentuated by country-specific circumstances. In China, a case in point of other emerging countries, demand for imaging studies grows faster than buildup of imaging capacity resulting in tremendous workload, reducing the time per patient, which, in turn, increases the risk of suboptimal imaging procedures and reading errors.

(5) Growing complexity & radiological education

While technological advances and increasing medical knowledge expand the areas of application of medical imaging and, hence, present a great gift for physicians and patients alike, they also make radiology ever more complex. A look at the decision support database of the American College of Radiology gives an idea of the vast amount of options and application parameters in diagnostic imaging. Against this background, 'clinical decision-support software' has become a great subject of debate in the USA and shall become mandatory by 2017/2018.[9] Continued training is an effective means to ensure that novel scientific discoveries and technologies find their way into clinical practice. Radiology has been at the forefront of continuing education: major radiology congresses, such as RSNA and ECR, attract thousands of radiologists from around the world each year. However, advances in radiology, nuclear medicine and in particular in oncology, will demand ever more effort and support for radiologists to keep pace with the progress and is likely to further increase sub-specialization in the field.

(6) Reporting & communication

Referring physicians, in particular, demand radiologists to standardize their reporting. Radiologists' reports often lack standardized formatting and language. This makes it more difficult for other radiologists and referring physicians to interpret the results and for software to automatically read and connect the findings to the patient data. Radiological societies have understood this challenge and work on standardized language and reporting not only to please the referring physician, but also to demonstrate the value that they add to patient management. Standardized reports will generate large amounts of structured data, which may potentially yield novel medical and disease insights/patterns across the radiology data and also in conjunction with further clinical data, as we will discuss later in this paper.

(7) Restrictive reimbursement

In an environment of medical cost containment, radiology is no exception to the rule. In the United States, for example, reimbursement rates were cut by almost 50% between 2000 and 2015[10]. Similar reductions can be seen in major European countries and in advanced Asian countries. What does this mean for the imaging discipline? Declining reimbursement affects the departments' disposable income for regular purchases and investment into imaging equipment and also limits the number of technicians and physicians that can be hired. There is a growing number of payers discussing value-based reimbursement as opposed to the current fee-for-service system. Evaluating the individual contribution of different actors to patient outcome is a difficult task – even more so for diagnostic disciplines. Elaborating appropriate solutions hereto will be a major challenge for radiology stakeholders.

3 Innovation drivers in medical imaging

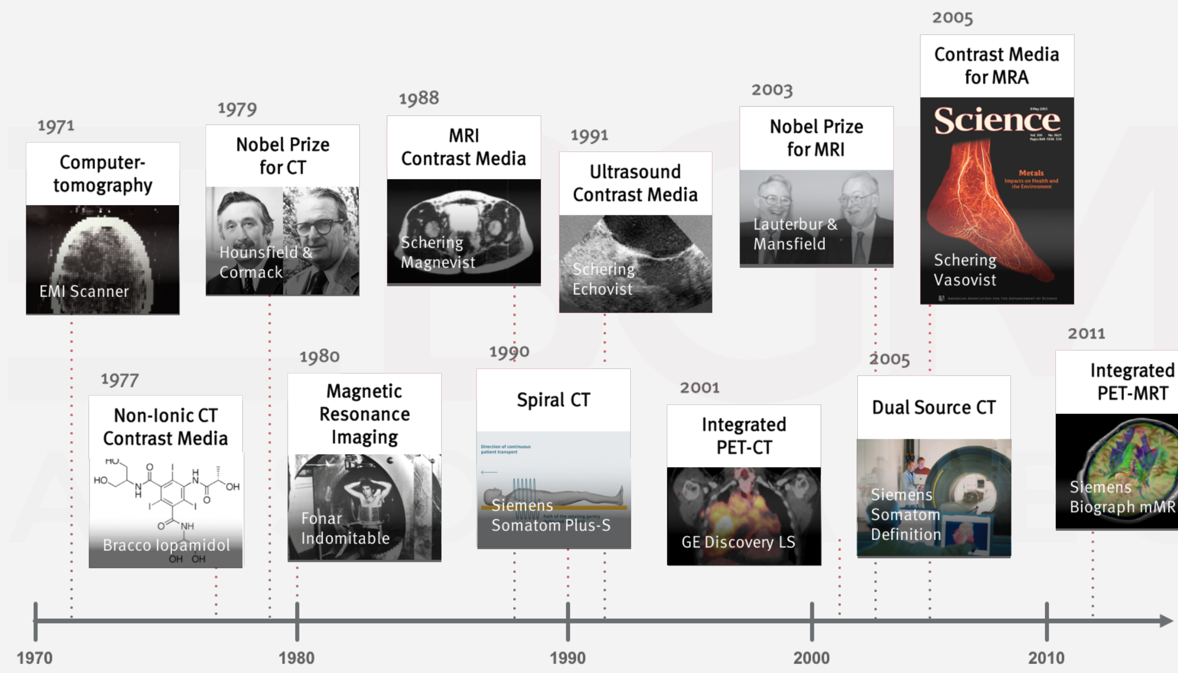
The current shortcomings and challenges, as well as medical and customer needs will be a major driver of innovation in imaging. Equally, both incumbent companies as well as industry outsiders continue to push innovative products into the market. While the past decades have shown major breakthroughs both in imaging devices as well as contrast agents (figure 2), we believe major innovation and quality improvement in future will be driven by software, in particular in its capacity to integrate the radiology ecosystem and facilitate the radiologist's work. In both imaging equipment and contrast media, we only expect incremental innovation.

Incremental innovation of equipment and devices

Across imaging modalities, the equipment manufacturers have made astonishing progress over the last decades. In CT, higher slice systems, iterative image reconstruction and spectral CT have contributed to significantly increase image resolution and imaging speed while reducing the dose both of radiation and contrast necessary to obtain high quality images.[11] This has greatly expanded the indications of CT imaging. While image resolution is expected to only provide little room for improvement, the manufacturers focus on dose reduction. In some indications, Siemens' latest CT generation requires only half the amount of contrast media than preceding generations. However, we do not expect native CT imaging to fully replace broad indications of contrast-enhanced imaging. Moreover, we may see an increasing number of dedicated CT devices, for instance in intraoperative and interventional applications, as well as specific indications, e.g. breast imaging.

Figure 2 The past forty years of innovation in radiology

Selected innovations and milestones



Source: BGM Associates; Images courtesy of Siemens Healthcare, GE Healthcare, Bayer, Fonar, Nobel Prize Media

In MRI, the manufacturers hitherto have focused on increasing the field strengths of the devices to improve resolution and contrast. While latest devices provide 7 and even 9 Tesla, their application will be refrained to research use. Without any doubt, 3 Tesla devices will expand their place in clinical practice. We expect that MRI machines will significantly increase speed, which will improve patient throughput and, thus, affordability in comparison to CT imaging. GE Healthcare, for instance, claims it is able to reduce the imaging time by two thirds with its new MAGiC software.[13] Moreover,

Fusion imaging with PET-CT machines has seen a great adoption in advanced markets after its introduction in 2001. In 2011, Siemens has introduced the first integrated PET-MRI scanner. The lack of radiation exposure from X-rays and the superior soft tissue contrast of MRI provide important advantages over PET-CT machines. The improving imaging time of PET-MRI also closes the gap to PET-CT.[15] A major obstacle remains the high price of PET-MRI scanners, which explains why these machines are currently largely limited to high-end research hospitals. However, we assume that PET-MRI will be adopted gradually in clinical practice for specific indications, for instance in pediatric imaging.[16]

Ultrasound imaging remains the first-line diagnostic tool in many indications. The image quality has greatly improved over the last decade. What we currently see is a continuous trend towards miniaturization as well as advanced software functionality that allows for real-time image fusion and real-time 3D image reconstruction (e.g. Toshiba's 'Fly through' technology).[17] The great challenge of ultrasound technology towards broader application remains its operator dependence. With recent advances in sensor technology and high-speed computer processing, new algorithms can be developed that take the ultrasound operators by the hand and guide the procedure as well as image interpretation. This may provide the chance to facilitate the use of ultrasound contrast media in existing indications, e.g. echocardiography, as well as in new indications such as prostate biopsies, which today are only performed by highly specialized university hospitals.

A major advance is multimodal image fusion and analysis. It enables fusion of images from different modalities that were taken from a patient at different occasions and time. Different modalities, such as CT, MRI or ultrasound are often complementary. A mammography for instance is the superior modality to detect microcalzification, while ultrasound allows differentiation of tumor and cyst. Mathematical models developed, e.g. by the Fraunhofer MEVIS Institute for Medical Image Computing in Bremen, Germany, allow accurate integration and analysis in one imaging framework thus enabling the radiologist to come up with a holistic assessment of the disease including characterization, differentiation and quantification.

Incremental innovation of contrast media and injection systems

Since the late 1920th and early 1930th continuous progress has been made to develop and improve imaging contrast agents.[18] Despite some side-effects, including allergic reactions, iodine based contrast agents are regarded as very safe and have established a "gold standard", which is very high and very difficult to match or even to improve with novel compounds. Research on novel contrast agents , has not yet yielded any significant breakthrough during the past decade, not to speak of a marketable product yet. Our prediction is that there will be no novel CT contrast agents entering the market within the next decade.

The same holds true for MRI contrast agents, which are more or less exclusively based on gadolinium, a rare earth with paramagnetic properties. Gadolinium came under scrutiny during the past decade, since multiple and probably overdosed use in particular in the USA in multi-morbid patients, led to the potentially life-threatening disease Nephrogenic Systemic Fibrosis (NSF). Also recent research has provided some evidence that Gadolinium may in certain cases be retained in the body for a long time and may not be fully excreted.[19] Nevertheless are today's MRI contrast agents extremely safe, in particular the so-called "macro-cyclic" products. They have established quality and safety benchmarks, which are hard to be beaten by any new development in the near and even more distant future.

Current iodine and gadolinium based contrast agents are here to stay and innovation in these segments will be confined to lifecycle management, working on new application protocols, lower doses and precise dose management.

Different from CT and MRI we see some room for R&D yielding results within the next decade in ultrasound imaging. Currently, the existing ultrasound contrast agents are primarily used for echocardiography and to a smaller extend also in other organs, for instance the liver, the breast and the prostate. While academia puts much emphasis on generating evidence on their value in off-label indications, Bracco also invests in the development of more targeted agents for angiogenesis and inflammation.[21] The adoption of contrast-enhanced ultrasound (CEUS) may also benefit from novel software solutions and ultrasound contrast injectors, such as Bracco's *Vueject Pump* and Nemoto's *Sonazoid Shot*. These solutions support "user independence" and thus make CEUS a much more reliable technique.

Without any doubt there will be novel radioactive labeled markers for Positron Emission Tomography (PET). However, we expect this field to stay largely academic, since major compounds such as FDG in a vast range of oncological applications, or more recently PSMA in prostate cancer, are not patent protected. All major companies who have invested in R&D in the past, such as Bayer, GE and Siemens have left the field. The only compounds that could gain significant commercial potential are tracers aiming at the detection of Beta-amyloid plaques, regarded as a hallmark of Alzheimer's disease. The potential success of these tracers hinges, however, to a great extent on the successful development of novel disease-modifying Alzheimer's therapies. Despite the tremendous effort and investment in Alzheimer's therapies, effective and safe compounds may still be far out in the future.

The accuracy and benefit of contrast agents depends to a great extent on the injection protocol. This applies in particular to CT, where the increasing speed of the imaging sequence requires a neat alignment of contrast injection and scanner protocol. In MRI, contrast injectors are still less adopted since the volume is much lower and time alignment less critical. That being said, a contrast injector provides benefit across all modalities by providing standardized and patient-specific protocols and consistent monitoring. While we do not see any disruptive innovations in this segment, we do expect that roll-pump based systems with continuous flow will increase their market share due to workflow efficiencies and hygiene advantages.[22]

Transformative innovation driven by software and data integration

Software is anything but new in radiology. Since the introduction of computed tomography in 1971, the processing of bits and bytes is fundamental to diagnostic imaging. What is new, however, is the growing importance of software solutions as a driver of quality and standardization and, hence, product differentiation.

In the next decades, software will be the major innovation driver in radiology. It will improve image acquisition through standardization, image interpretation and diagnosis through computer-assisted detection algorithms, and communication of results through improved platforms for standardized reporting and image sharing.

Over the last three years, we have seen a strong increase of interest in software for quality management and dose tracking in radiology. Bayer's acquisition of Radimetrics was followed by many companies developing suitable solutions. This quest for more standardization in radiology is also exemplified by Clinical Decision-Support (CDS) software that assesses the appropriateness of a physician's diagnostic exam order and ultimately leads to the selection of standardized imaging protocols for more consistent imaging quality. The American College of Radiology pushes this field with its own software solution under the umbrella of the National Decision Support Company.[23]

The probably greatest progress in diagnostic imaging will be brought about by advances in machine learning. The growing amounts of data and images to be read by radiologists call for computer support in reading and interpreting the data. This is intensified by the fact that in many regions of the world, we do or will face a shortage of skilled radiologists. It is likely that algorithms will achieve a much higher reading accuracy and consistency than human beings. Today, computer-assisted detection (CAD) and advanced visualization tools are only used in selected indications, such as mammography or the quantification of tumors. But academia and the industry are developing software solutions capable to assess much more indications. IBM's Watson is just the tip of the iceberg of ongoing initiatives to make radiology software intelligent and self-learning. Startups such as Arterys, Enlitic, Zebra Medical as well as top-notch scientific institutions such as Fraunhofer MEVIS collect huge amounts of image data to apply machine learning and deep learning algorithms to train computers reading these images. Enlitic claims that their algorithm was 50% more accurate in detecting lung cancer nodules than an expert panel of thoracic radiologists.[25] This is the beginning of a new era of data-driven medicine. While first applications now become commercially available, we expect this technology to progress indication by indication. Zebra Medical, for instance, has released a tool to assess patient risk for osteoporotic bone fractures based on pre-existing CT studies.

The computer is not going to replace the radiologist within the next decade and probably not at all. Without any doubt, however, it will change the work and role of the radiologist and improve overall quality consistency. CAD will become indispensable for the fast recognition of disease patterns, the speedy differentiation of "normal" and suspected tissue, differential diagnosis and therapy decisions.

The reconfiguration of global imaging value chains

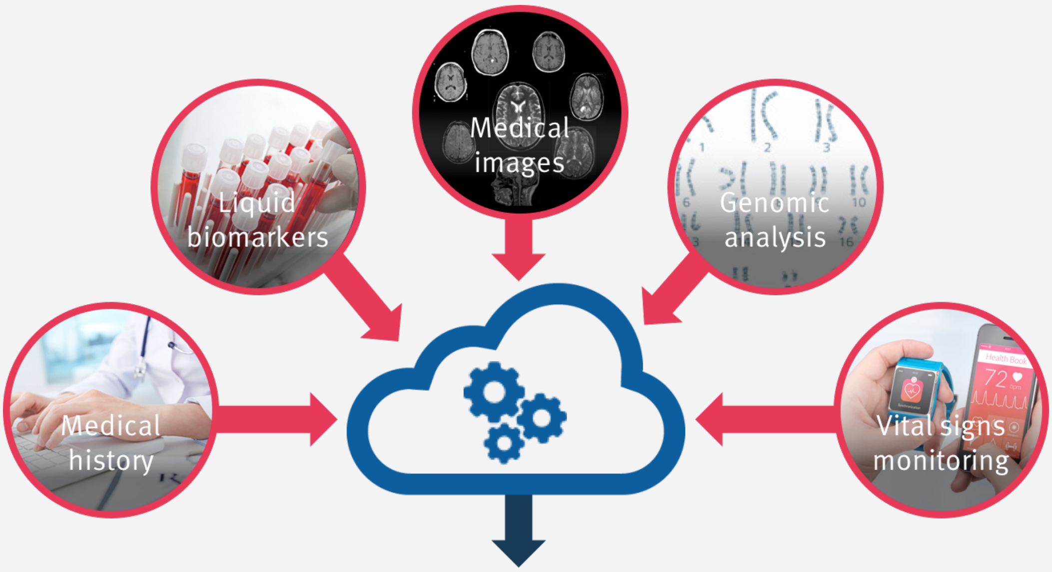
Already today, the acquisition of medical images and image reading as well as diagnosis is often separated. Based on fast image transmission, it is possible to acquire e.g. a sequence of CT images in the Chinese hinterland and do the post-processing and diagnosis by a specialist in Shanghai, Beijing or any other place in the world in a matter of minutes. And this of course is not only important in large territory countries but also in the countryside of e.g. Germany, which by no means has top-notch radiology infrastructure and specialized know-how available everywhere. Already today tele-radiology provides emergency radiology in small and remote hospitals and clinics. Global value-chains, as we know them already from a great number of industries will become reality also in medicine and healthcare industries and bring about new business models in the imaging service provider landscape.

4 Convergence of diagnostic disciplines

Modern medicine has an incredibly large set of patient data on file and every day this data pool is growing at an extraordinary speed. The pool of data comprises medical images, laboratory data, such as blood, saliva and urine, histological insights, genomic information, and patient records of all sorts. The recent advances in genome analysis brought new tools to the table to assess individual risk factors and to identify and characterize cancer based on tumor DNA circulating in the blood. Some companies have started larger scale clinical trials with their liquid biopsy tests, but fully reliable tests with high sensitivity and specificity may probably still be years away from the market.

While IVD test results are structured data by nature, both radiological images and pathological information were difficult to structure and quantify in the past. With the advances in imaging software, the adoption of digital pathology labs, and novel more powerful algorithms, we now have the foundation to really integrate these diagnostic disciplines. This is further complemented by novel popular health apps and wearable sensors that help monitoring activity and vital signs day and night.

Figure 3 Information technology and big data converges diagnostic disciplines



The automated analysis of hitherto largely unconnected medical data sets promises faster and more accurate diagnosis and therapy monitoring, as well as the identification of pathological disease patterns

Source: BGM Associates

The volume of stored healthcare data is expected to increase tremendously in the next years from roughly 150 exabytes in 2015 to 2,300 exabytes in 2020. It is undisputed that intelligent analysis of large patient data pools will probably render important new insights into disease patterns, disease histories, and the interaction of genomic pre-dispositions and acquired disease factors. Despite high legal hurdles and technical challenges in using patient data, the benefit of big data analysis for the advancement of medicine will probably prevail. This provides new opportunities for actors along the value chain to take advantage of and drive the integration of diagnostic disciplines.

5 Conclusions for the imaging industry

The incumbent imaging equipment manufacturers face increasing competition from new entrants, such as the South Korean electronics giant Samsung that has recently presented a 128-slice high-end CT machine with a speed of 0.25 s per rotation[30], China's Neusoft Medical that has recently received CE-clearance for its 128-slice CT machine in Europe[31], or also Mindray of China. It will be hard to compete with only incremental innovation and lifecycle management. These companies are closing the technology gap and build organic sales and service capabilities through partnerships, acquisitions and high-profile hires. These challengers will not only compete on price but also go for high-end solutions and incorporate incremental innovations.

While key contrast agents for enhanced X-ray and CT imaging are already off patent, remaining protected key products in MRI face the patent cliff in the years to come. Already today a significant number of generic players from Japan, Korea and China, but also Europe, have entered the market and are likely to capture a growing share of the market. With the recent acquisition of Mallinckrodt's contrast media and delivery systems business by Guerbet, the consolidation process has been kicked off. Guerbet now forms a EUR 800 m company going head to head with Bayer's, Bracco's and GE's contrast media businesses.

If our assumptions are about right that only incremental innovations will come from current incumbents in both the equipment as well as the contrast media and injector industries, with price pressure as well as competition increasing in all segments – scanners, contrast media and injectors – the question is, how will these companies adapt to the challenges and opportunities described above. How can they survive?

Of course, one defense strategy could be mergers and acquisitions to increase market-share and achieve better economies of scale across the company value chains. However, in the long run only those players will defend their turf and grow that invest in new technologies and embrace collaboration beyond the current company boundaries. The incumbents need to build ambidextrous organizations that are capable of simultaneously exploiting existing competencies and exploring new opportunities.[32]

The shortcomings and innovation drivers outlined above provide some interesting avenues for strategic exploration that we roughly sketch hereafter in five archetypes.

The radiology integrator: Radiology still holds opportunities in the intelligent integration and standardization of so far highly fragmented radiology workflows in terms of quality and efficiency enhancement. Using the analogy of Apple Inc's ecosystem, imaging companies could build competitive advantage by developing an integrated imaging ecosystem where scanning devices, contrast injector, as well as decision support and image interpretation software are a single system that facilitates and optimizes the entire imaging operation.

The service specialist: The growing emphasis on value and cost containment favors professionalized imaging services. Now that private imaging centers and radiology outsourcing providers grow around the world, the imaging service market provides an interesting option for forward integration. This business model further gains in attractiveness due to the increasing value of structured data that could be used to further optimize image interpretation software.

The big-data innovator: Information technology is currently creating a whole new market segment in medical imaging and diagnostics. With the ever increasing volume of medical data and the shift of data storage into the cloud, there is a new market segment for healthcare information systems emerging. With this comes the need for new tools and learning algorithms to extract value out of the data. This attracts new players from the information technology and also the consumer electronics side that enter the market for diagnostics and imaging. The names are IBM, Apple, Google, Amazon, SAP and many smaller players and start-up's who's names we may not even know today.

The diagnostics integrator: Some companies have pursued the vision of integrated diagnostics – to date with only modest success. A case in point is Siemens Healthcare with its acquisitions of Bayer's and Dade Behring's IVD businesses in 2006 and 2007 respectively. Siemens aimed for a comprehensive portfolio in diagnostics and for integrated solutions that would yield benefits from both fields. Now that we possess more powerful ways to connect and analyze data, it may become possible to integrate and optimize the entire diagnostic workup of an individual patient including in-vitro diagnostics, pathology and imaging as a service for private practices, clinics and hospitals as well as self-paying customers.

The therapeutics explorer: The importance of medical imaging for therapy grows steadily. Not only does interventional radiology grow in adoption, thanks, in particular, to breathtaking innovations in minimally-invasive surgery. Imaging is also a critical component for all forms of surgery as a guidance tool and for therapy follow-up as a means to monitor therapeutic success. Some imaging companies could leverage their current technologies and understanding of medical workflows to develop novel products and image-guided therapies. Likewise established medical technology companies such as Medtronic, St. Jude or Abbott, or even pharma players could make inroads from the other side.

Medical imaging and its adjacent fields provide various avenues for strategic exploration. Some of these may require companies to reinvent themselves and build new capabilities and customer relations beyond their current core business. Organizational research tells us that it can be challenging to overcome the legacy of a company and to implement such significant change. With a culture embracing open innovation and partnering, however, companies can overcome such barriers and explore new opportunities while they exploit their current activities. Their 'absorptive capacity' to acquire and integrate new knowledge, technology and specialists from adjacent fields will be critical to success.

Join the debate

We kindly invite the readers to discuss our hypotheses and working conclusions with us. You can reach the authors by phone and by mail:

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About BGM Associates

BGM Associates is a strategy and transaction advisory firm with an industry focus on healthcare and life sciences. Founded in 2012, we are a team of six consultants in our head offices in Berlin and our Asia liaison office in Seoul.

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