The Role of Imaging Physicians in Industry

Recent trends in medical care and reimbursement have impacted the physician job market in general, including that for nuclear medicine physicians (*1,2*).With the advent of PET/CT, PET/MR, and an increasing number of new tracers in development, it is clear that a new training pathway including both functional and anatomic imaging is becoming essential (*3*). The executive committee of the European Association of Nuclear Medicine is focusing on visions and strategic goals for the future of nuclear medicine, the ways in which multimodality imaging can be shared with our logical partners, and the ways in which service to clinicians can be improved so that they understand the value of nuclear medicine (*4*). Although the majority of nuclear medicine physicians practice in clinical nuclear medicine in hospitals or private practice centers, an increasing number of opportunities are now available for careers in nontraditional practice settings in industry.

As outlined in our recent Newsline communication (*5*), opportunities in industry for nuclear medicine physicians are arising from a growing recognition of the role of imaging biomarkers in drug development. Nuclear medicine physicians are well suited to positions in industry because their molecular imaging expertise complements the existing skill set already present in industry. For example, CT and MR scans can be incorporated in clinical trial design and implemented in clinical trials by a knowledgeable nonimaging physician, whereas most nonnuclear trained physicians are less comfortable with designing a trial with more exploratory molecular imaging techniques.

The imaging physician's role in industry is quite different from that in clinical nuclear medicine. Indeed, working in industry might be equated with learning a different "language" that must be acquired to interact in the culture of the workplace. Imaging physicians in industry must also be successful in effectively communicating and participating in project teams with contributing members spread across the globe. Physicians constitute one of the many essential pieces of each puzzle, a role that necessitates leveraging the entire project team's ideas and capabilities. Imaging physicians, along with other physicians on a project team, are ultimately accountable for the success of the project.

An apparent disadvantage of working in industry (or perhaps a bonus for some) is the lack of patient contact. Although clinical nuclear medicine is today mainly a diagnostic specialty with decreasing emphasis on direct patient care, some diagnostic procedures and therapies require physician contact with patients. Although an MD still works as a physician in the pharmaceutical industry and ultimately helps patients through innovative diagnostic or therapeutic research, most positions are devoid of patient contact. Opportunities for patient care are available in some companies that run their own early-phase research units. When working for industry, however, it often becomes problematic for the physician to return to the clinic because of perceptions that an individual working in industry may have lost clinical skills or may not be up-to-date on the latest clinical guidelines. An ideal situation, although difficult in practice, is a combined career in both industry and part-time clinical work.

Most companies have "matrixed" reporting structures, and some experience in working in such an environment is desirable. Matrixed structures are implemented in large projects or product development processes organized and managed in such a way that individuals from different functional disciplines work together as a team without being removed from their respective positions. In addition to different corporate structures, practice in industry involves assuming a more "business-like" demeanor. Written communications, including e-mails, must be carefully crafted and executed. Equally important is the ability to communicate effectively to an audience with varying but complementary skill sets, to attain "stakeholder" or "line function" buy-in, and to effect positive change in attitudes and morale to advance a project. Employers in industry often seek prospective employees with some direct or indirect exposure to industry settings. Examples of exposure include designing and directing preclinical and clinical research studies and direct or affiliated roles working with industry.

A variety of imaging physician or imaging project leader positions are available in biotech companies (biotech), pharmaceutical companies (pharma), and contract research organizations. In addition, clinical project leader, safety, medical affairs, and marketing positions are available in tracer and therapeutic drug development.

Imaging Biomarkers in Research Trials

During the past 30 years, our understanding of the molecular, cellular, and tissue processes in organisms has substantially advanced, but the development of safe and effective drug therapies remains slow, inefficient, and expensive (*6*). Introducing a novel drug to market takes 10–15 years and costs US $4 to $11 billion (*7*). Adding to these challenges is a high attrition rate for promising innovative drugs in late-stage clinical trials, because many studies fail to demonstrate the clinical benefit that is required for marketing approval. Lack of demonstration of clinical utility may not indicate that the drug is without utility, but, instead may be the result of testing the drug in an inappropriate patient population or designing a study without a clear clinical endpoint.

To that end, biomarkers, including imaging biomarkers, may be useful throughout the drug development continuum to identify and validate therapeutic targets, screen and optimize candidate agents, provide proof of concept for agents and models, and enhance mechanistic understanding of drug or rational drug combinations. In both drug development and

clinical practice, biomarkers can help identify optimal patient target populations, stratify risk, predict response or resistance to therapy, identify toxicities related to therapy, and distinguish early responders from nonresponders to therapeutic interventions (*8*). Imaging physicians currently play a crucial role in facilitating the development of safe and effective drugs in industry. The SNMMI Center for Molecular Imaging Innovation and Translation (CMIIT; previously the Molecular Imaging Center of Excellence) Education Task Force has compiled a compendium of molecular imaging resources for physicians and scientists on the SNMMI Web site to help explore incorporating more recent and advanced principles and techniques of molecular imaging (e.g., new radioactive and nonradioactive tracers and MR and optical imaging techniques) (*9*,*10*). In addition, CMIIT has been actively engaged in the design of educational programs, including a revised curriculum, "Nuclear Medicine Residency Curriculum Resource Compendium," in 2008. In 2011, new nuclear medicine residency program recommendations included an increased emphasis on molecular imaging in clinical practice, and the American Board of Nuclear Medicine published a position statement that now incorporates professional competency in new molecular imaging probes in preclinical investigation and in their transition to the clinic (*11*–*13*).

Different stakeholders in drug development are working in different "spheres." For example, patients and health care payers and providers operate primarily with clinical endpoints, whereas academicians' work traverses all the various endpoints, the ranges of qualified biomarkers, and the exploratory and highly exploratory categories (Fig. 1).

Multisector cooperation for identification, validation, review, and implementation of imaging biomarkers and surrogate endpoints in drug development is becoming increasingly critical. Successful collaborations among public and private sector advocates—patients and their advocacy groups, government, pharma, biotech, and academia—have outlined strategies in the application of imaging biomarkers for more effective cancer drug development (risk stratification, clinical trial design, endpoints) and to advance research into new technologies in correlative imaging biomarker methodology and validation in phase I, II, and III oncology drug trials (*14*). Hillman et al. recently described another great example of multisector collaboration where the Molecular Imaging and Technology Alliance has described potential reimbursement strategies for novel imaging agents and suggestions to establish a new framework for coverage of novel tracers so that these could rapidly enter the market (*15*).

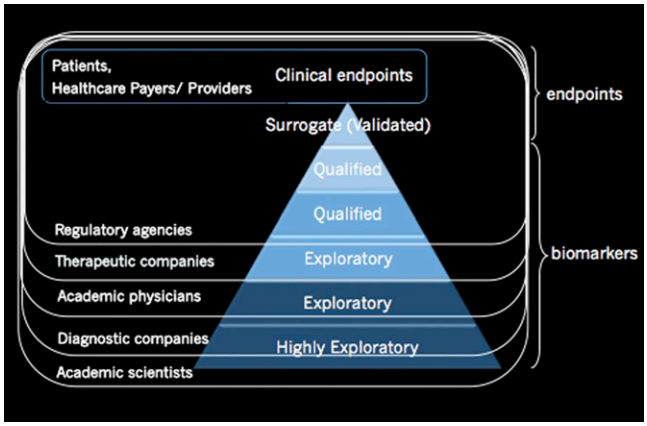

FIGURE 1. Biomarker hierarchy. Endpoints can be described as either clinical or surrogate endpoints. Biomarkers range in degrees of their qualification and may vary from exploratory to highly exploratory. Regulatory agencies, therapeutic companies, academic physicians, diagnostic companies, and academic scientists may all be discussing biomarkers, but communication is sometimes difficult because these groups are working in different spaces.

CONCLUSION

In the age of personalized medicine, opportunities are available in industry for careers beyond traditional clinical practice. Nuclear medicine physicians are well trained for careers in industry because of their unique expertise and insights in molecular imaging.

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