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## EDITORIAL

# Imaging technologies

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Developing a new drug is time-consuming and expensive. Many drugs fail at a relatively late stage in their development process, often owing to disappointing results in clinical trials. There is increasing evidence that imaging technologies could provide an important contribution towards savings in both time and money. In many cases, imaging studies could be incorporated in the drug development process before the start of large clinical trials, for example, in combination with Phase I studies or even at the stage of preclinical evaluation (imaging studies in experimental animals). State-of-the-art imaging techniques are, however, complex technologies. The level of complexity is enhanced by the fact that, especially for many drug development purposes, the content within the images often needs to be quantified for full interpretation of the results. For example, in dose ranging studies, extracting specific binding from (a series of dynamic) PET images is mandatory for assessing receptor occupancy. In other words, imaging technologies not only are complex in their own right, they also have to be operated at the front end of their capabilities. Consequently, it is extremely important to be aware of both these capabilities and the inherent limitations of the various imaging techniques. Selection of the most appropriate imaging technique depends on this knowledge in combination with the (research) question to be addressed. To avoid disappointment, it is important to assess (at a very early stage of study design) whether and how a specific question can potentially be answered with one of the imaging technologies available.

The present issue of *Drug Discovery Today: Technologies* is devoted in part to imaging technologies and how they can be used in the drug development process. It contains a selection of monographs on various relevant issues, written by leading

### Box 1. Section Editor

#### Adriaan A. Lammertsma

Professor Dr Adriaan A. Lammertsma studied physics at the State University Groningen. He has been involved in PET since 1979 when he moved to the MRC Cyclotron Unit, Hammersmith Hospital, London. In 1984, he received his PhD in Medicine from the University of London on the use of PET for measuring blood flow and oxygen metabolism. With the exception of a one-year sabbatical leave at UCLA, he stayed at Hammersmith until the end of 1996. He then moved to the VU University Medical Centre in Amsterdam, where he is now head of the Department of Nuclear Medicine & PET Research.



experts in their field. Reading the respective contributions will emphasize the notion that the use of imaging technologies for drug development is by no means an easy option. By contrast, the contributions will highlight the unique information that can be obtained by imaging technologies, potentially leading to a significant reduction in drug development costs. The main message is that significant advances can be made, provided that (1) the most appropriate imaging technology is selected and (2) attention is being paid to study design. It is hoped and expected that the present issue of *Drug Discovery Today: Technologies* will assist in this process.

With best wishes,

**Adriaan A. Lammertsma**

# Biomarkers and surrogate markers

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We are now witnessing an exciting and rapid advancement of genomic and proteomic sciences, including the completion of the human genome sequence, the release of the International HapMap data providing the extensive catalog of human genetic variation and the acceleration of technologies to assess such variations combined with new views of the proteome and novel methods to detect proteomic changes. We hope to herald an era whereby crucial new insight into human disease state, progression or response to therapeutic intervention to advance our understanding of human disease and therapeutic effects can be realized.

Yet at the same time, the challenges of bringing effective new medicines to the marketplace loom large. The pharmaceutical industry faces increasing development costs and rising attrition figures resulting in decreasing industry productivity. The ability of the industry to make better informed decisions, whether to go forward or in many cases to stop financial investment in a particular compound or mechanism of action, at early stages in clinical development has been aligned with a growing focus on biomarkers defined as 'a characteristic that is measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to therapeutic intervention'. Yet many obstacles and technological advances remain to effectively identify, develop, validate and apply relevant biomarkers throughout the drug discovery and development continuum.

In this edition of *Drug Discovery Today: Technologies*, we bring together a series of articles that focus on biomarker sciences which seek to enable the practical application of biomarkers. Similarly, clinical programs with rich phenotypic data serve as the foundation for the design and execution of biomarker studies which impact the pharmaceutical pipeline

## Box 1. Section Editor

### Patrice M. Milos

Dr Patrice Milos is currently a Director with the newly created Molecular Profiling line within the Pfizer Clinical Research and Development organization. She joined Pfizer in 1993 as a member of the Atherosclerosis Molecular Sciences team. In 1996, she shifted from the therapeutic area to help start and grow the Discovery Pharmacogenomics organization. In 2002, Patrice assumed additional responsibility for the Groton Translational Biomarkers group, one of the first translational biomarkers groups within PGRD. Before joining Pfizer, Patrice worked in the biotech arena developing animal models for human disease. She received her PhD from Rensselaer Polytechnic Institute in 1984 and completed post-doctoral fellowships at Harvard University and Brown University. Patrice has often represented Pfizer at key external meetings and she and her team have authored many articles in the area of pharmacogenomics. Patrice also serves on several



from early discovery through to the marketplace. An essential component thus includes the ability to leverage existing clinical information with associated biological samples and thus we extend enablement to include the crucial information requirements needed to fully capitalize the investments made to realize biomarker value.

With best wishes,  
**Patrice M. Milos**