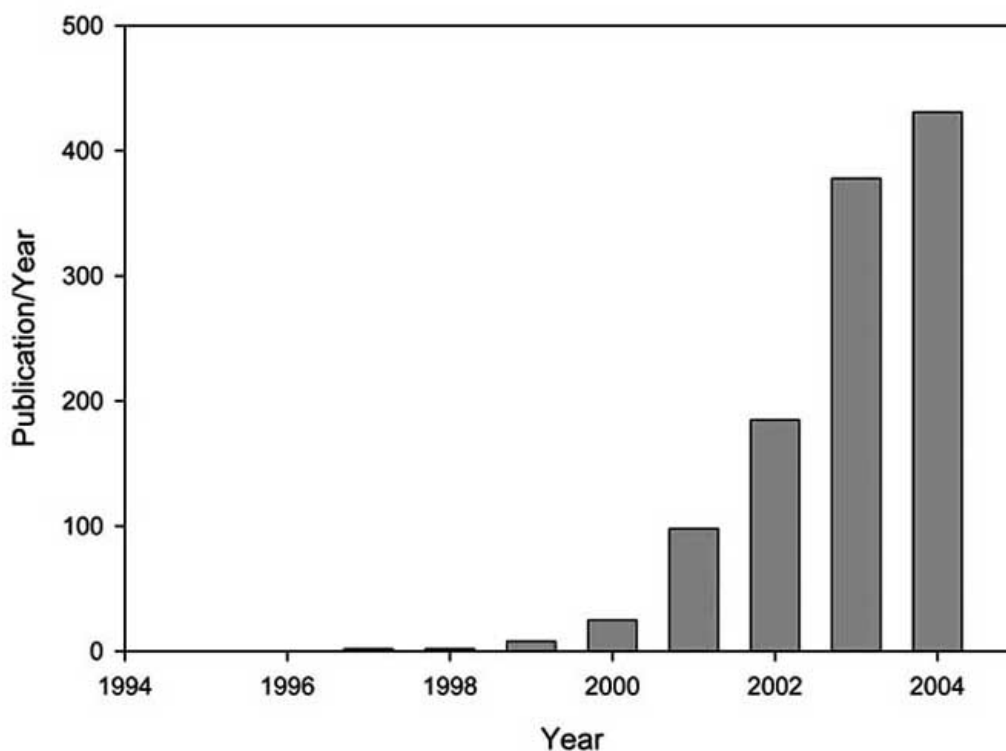


Editorial

What will drug development look like in 10, 20 or 40 years? Opinions abound on this interesting question, ranging from totally personalized development of medicines, (visions of Scotty in Star Trek using his scanner to diagnose and treat Captain Kirk on the spot!) to multifunctional drug targets that can be used across a wide range of disease indications. As the landscape in drug development is rapidly evolving, there are heightened expectations that we should reap the benefits of the genomic revolution, increased pressure for better drug safety, and price pressure from generic medicines and consumer demand. Within this rapidly evolving environment, new technologies are being developed that will likely change the face of drug discovery and development. Prominent among these is the fledgling enterprise of transcriptome analysis.

Transcriptome analysis provides the opportunity to evaluate global changes in gene transcript expression in a cell, tissue, organ or whole organism. Within the past decade there has been an exponential increase in publications on transcriptomics (see the Figure), with several significant advances already seen. This issue is dedicated to exploring how transcriptome analysis is impacting drug discovery and development, and to allow the reader to become familiar with the application of this technology within this context.

Transcriptome Publications Per Year



Results from a search of Current Contents of transcriptome or transcriptomic or transcriptomics on a yearly basis. The data for 2004 are to week 49.

The issue is divided thematically into two groups of articles. The first five articles discuss the technology, how it is used, how to approach data analysis, and how this technology fits into the larger picture of available and developing technologies. Fan and Hedge explore the use of blood as a tissue for transcriptome analysis, guiding the reader into the intricacies and potential pitfalls that can be encountered. Yue and Residorf discuss

the various methods of data analysis that can be applied to transcriptomic data, and which analysis tools are currently available. Manasco discusses the ethical and legal implications for the use of transcriptome and genomic data, with potential solutions to various issues of confidentiality and consent proposed. Hu, Kaplow and He describe the lessons we have learned from use of traditional biomarkers and how this can be applied to transcriptomics. To put the use of this technology into a broader context, Bilello discusses how "OMIC" technologies can complement each other, and how the parallel fields of proteomics, metabonomics etc. are developing. These papers should serve to orient the reader to understanding in a general sense how transcriptomics can be applied in studying drugs.

The papers that follow deal more specifically with the use of transcriptome analysis in the various stages of drug development. Searfoss, Ryan and Jolly describe use in pre-clinical toxicology studies. In the clinical realm, Hsu, Cass and Williams discuss the use of transcriptomics in clinical pharmacology, which in general comprises the earliest stage of drug development. This is followed by three papers that discuss what has been to date the most widespread application of transcriptomics in drug development, namely in oncology. Burczynski and his collaborators discuss early phase oncology trials, while the papers by Dracopoli and Wadlow & Ramaswamy discuss later stage and additional uses in the oncology setting.

Overall, the reader should come away with a good understanding of how transcriptomics is being used and its potential applications. Clearly we are on the verge of a new era in drug discovery and development. The papers within this issue set the stage for the revolutionary impact transcriptomics will have on every aspect of pharmaceutical research and development.

I would like to thank all the authors for their diligent work on these manuscripts. It has been a pleasure and a privilege to edit this special issue.

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