FROM THE ANALYST'S COUCH

Unlocking the power of translational medicine

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With approximately 90% of phase I compounds failing to reach the market (*Nat. Rev. Drug Discov.* **15**, 379–380; 2016), high attrition rates remain a major obstacle for the biopharma industry. To help tackle this challenge, many companies are looking to the discipline of translational medicine (TM). To understand the progress that has been made, we conducted a survey of TM leaders from 25 of the top 50 pharma and biotech companies in the United States and Europe. We adopted a broad view of TM, and included all efforts from preclinical to late clinical development. TM practices integrate scientific (for example, biomarkers), technological (for example, in vitro testing modalities) and methodological (for example, in silico trials) advances to both enable more effective decision-making in R&D and enhance coordination not only among functions within a biopharma company but also with various industry, academic and government players.

Survey responses

All the survey respondents agreed that TM is an important means to improve clinical outcomes, accelerate R&D activities and develop more personalized medicines. However, there was a spread in how companies viewed the current role of TM: from "the core of all our drug development activities," to less central to their R&D organization. Nonetheless, the same nine functions reported to a head of TM in two-thirds of the companies surveyed, with some differences in their nomenclature (preclinical drug metabolism and pharmacokinetics, preclinical toxicology, clinical pharmacology or pharmacokinetics/pharmacodynamics, modelling and simulation, biomarkers and assays, biostatistics, imaging, early clinical development, and phase I–II clinical operations).

When asked to identify the greatest challenge facing their TM groups, 76% of respondents pointed to the difficulty in defining clear metrics to measure long-term success, given the additive impact of TM activities on the overall R&D productivity (FIG. 1). Without a means to measure TM influence, it is very difficult to communicate the value of TM to the broader organization — just 10% of experts reported that TM's positive impact on R&D is clearly articulated and recognized in their organization. Other important challenges identified include finding the right talent and setting up the governance structure that ensures TM input is reflected in the decision-making process, each of which was named by 48% of respondents.

Most respondents (92%) agreed that aligning TM groups with therapeutic areas is crucial or beneficial in allowing companies to both build specialized expertise and capabilities, and communicate and implement ideas in a timely way. Sixty percent of TM groups were aligned with a therapeutic area (for example, oncology or central nervous system disorders) and reported directly to the head of research or development for that therapeutic area, while 32% were aligned with therapeutic areas ▸

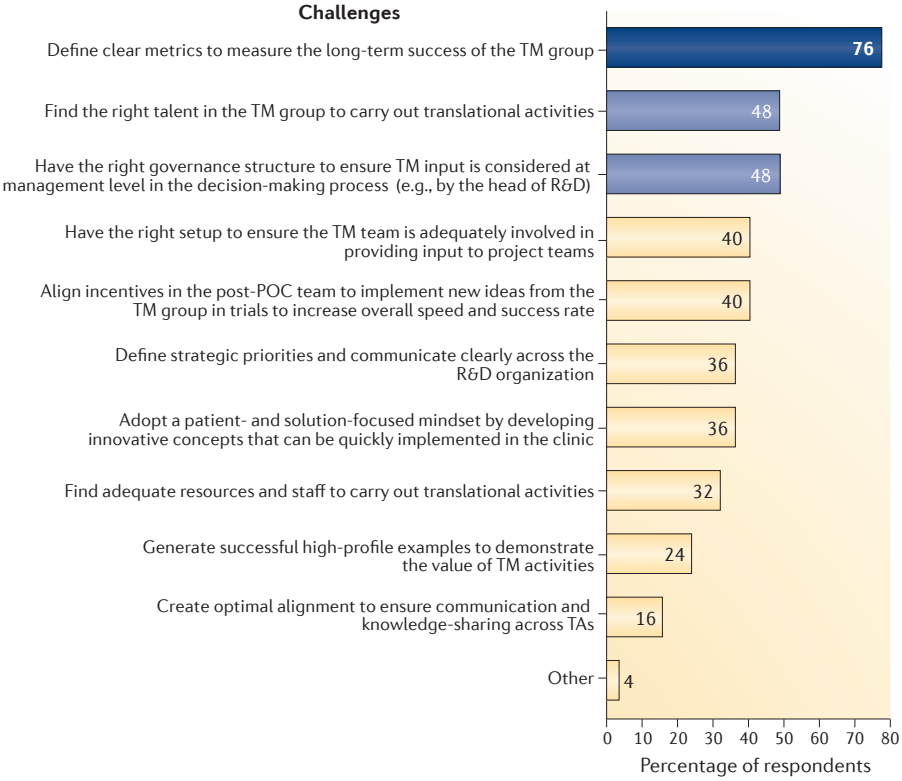

Fig. 1 | **Challenges for translational medicine groups in industry.** A survey of managers and heads of translational medicine (TM) from 25 of the top 50 pharma and biotech companies indicated that the greatest challenge for translational medicine groups is the lack of metrics for measuring impact. Of the 25 companies, 7 were in the top 10 pharma companies by size in their respective countries; 9 were in the top 11–20; 4 in the top 21–30; 3 in the top 31–40; and 2 in the top 41–50; 52% percent of the companies were located in the United States and 48% in Europe. Survey respondents were in their post in 2014 or later. The roles and ranks of the survey respondents varied from early clinical leader and senior manager of translational medicine to personalized medicine expert and translational medicine scientist. Survey responses were recorded at the level of individual institutions, with each response given equal weight. POC, proof of concept; TA, therapeutic area.

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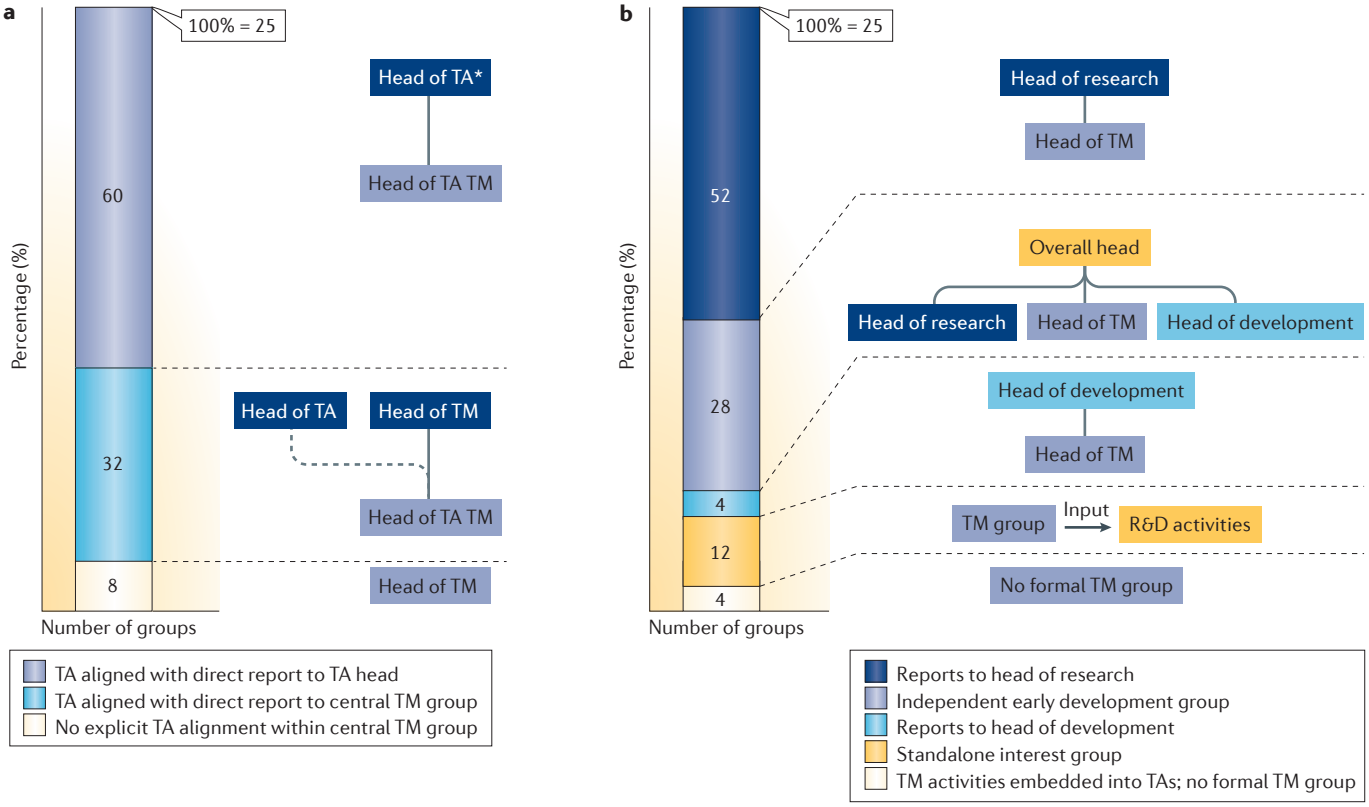

Fig. 2 | **Organizational alignment and structure of translational medicine groups in the industry.** The survey of leaders from 25 major biopharma companies indicated that translational medicine (TM) groups are primarily aligned by therapeutic area (TA) (part **a**), and have implemented a variety of organizational structures (part **b**). *In some cases, the TA head is the TA head for research and in others is the TA head for development.

but reported to a central TM group; only 8% operated across therapeutic areas (FIG. 2a). No single overall TM reporting structure was dominant, but most companies in the survey followed one of two models: 52% had a head of TM reporting to the head of research for a therapeutic area (in one company surveyed, in which there was no specific therapeutic area alignment, the head of TM reported to the overall head of research), and 28% established heads of TM, research, and development at the same level, with all three reporting to the head of R&D (FIG. 2b). Respondents agreed that TM must collaborate across the R&D value chain irrespective of reporting lines to speed up drug development, yet relatively few companies were rigorous (in their own judgment) in implementing TM input. For instance, although 88% of respondents considered TM group members core to their pre-POC (proof of concept) project teams, only 38% agreed that these teams treated TM input as a key consideration in their decision-making. This trend may be driven by the difficulty of establishing TM's impact on preclinical and early clinical development without clear metrics.

Recommendations

To strengthen the foundations of TM in the near-term, companies could take actions such as defining metrics to assess TM impact, optimizing their governance to enable collaboration among TM, research, and development (pre-POC and post-POC), fostering knowledge-sharing across therapeutic areas, and finding and retaining the right talent.

In the longer term, we suggest three key actions. The first is building capabilities to partner with institutions driving innovation in translational sciences, such as academia, government organizations and technology companies. These partnerships can help to build and better interrogate fuller data sets and inject new translational ideas to accelerate medical innovations from bench to bedside. 64% of respondents felt their organization was not yet a leader in forming and managing such partnerships. Second, companies could make better use of big data and machine learning. Although respondents acknowledged their importance, only a few had adopted novel practices such as using advanced computational power to link available data to identify new drug targets. And third, companies could more consistently involve TM in post-POC work. Only one respondent reported the integration of patient and disease insights into activities across the R&D value chain. Providing incentives for post-POC teams to implement transformative ideas from the TM group could be a lever to embed TM in the full R&D cycle. By strengthening current TM practices and preparing for expected TM advances, we believe that organizations could enhance the power of TM and increase its influence on R&D productivity overall.

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Competing interests
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