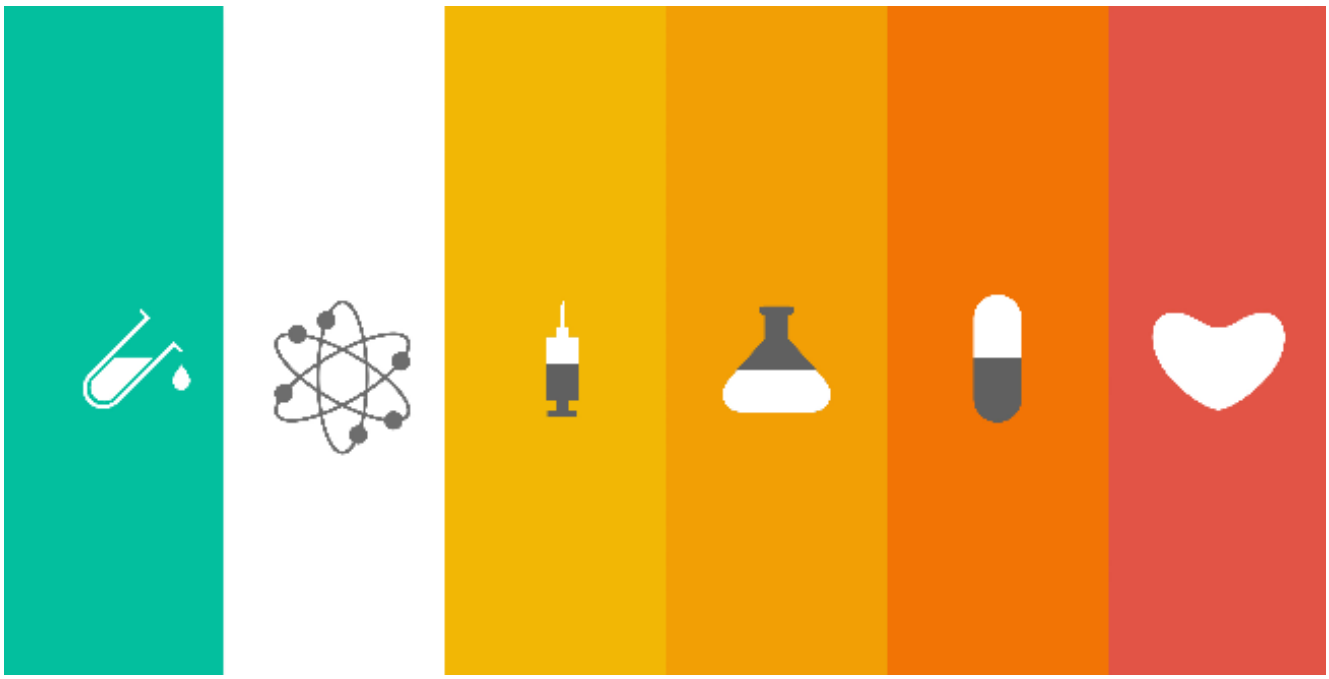
Personalized Medicine

What Pharma Should Do To Get Ready



Diaceutics GROUP

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Introduction

An essential component of personalized medicine is diagnostic testing, which identifies the right patient for the right drug. The diagnostic industry is growing steadily, but what does it mean for the pharmaceutical industry and how can pharma seize this personalized medicine opportunity? We reveal the actions and activities essential for companies that are determined to move ahead.

This Ebook has been created from a series of Expert Insights written by **Tessa Sandberg** and published by Diaceutics in 2015. We hope it will be a useful tool for initiating discussions, creating awareness within your team about diagnostic planning and getting you ready for a future in personalized medicine.

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What Pharma Should Do to Get Ready: An Introduction

The first class of an entrepreneurial program teaches students that change goes hand-in-hand with opportunity. At the moment, the clinical world is experiencing a revolutionary shift towards personalized medicine (PM) and so a huge opportunity is being created. But what should pharma do to capture this opportunity? Tessa Sandberg examines this in a series of Expert Insights called *Personalized Medicine: What Pharma Should Do to Get Ready* and reveals the actions and activities essential for companies that are determined to move ahead.

At the beginning of 2015, President Obama announced that the USA will invest $215 million in the 2016 budget to launch the 'Precision Medicine Initiative'. Precision medicine, or personalized medicine as it is known outside the US, is considered to be the most promising and revolutionary health care approach of our time—an approach which aims to treat the right patient with the right drug at the right time. It is different altogether from the old 'one-size-fits-all' treatments where the same drug can be very successful for some patients but not for others.

An essential component of personalized medicine is diagnostic (Dx) testing, which identifies the right patient for the right drug. The diagnostic industry is growing steadily, but what does it mean for the pharmaceutical industry and how can pharma seize this personalized medicine opportunity?

Entrepreneurs can come up with brilliant ideas but the greater challenge is to make the idea become a reality. Like the entrepreneur, you may have already identified the ideas behind personalized medicine, but a lack of experience within the team, or even the whole company, means you don't know how to move forward. Perhaps some of these scenarios sound familiar:

- You have probably noticed that Dx development should be aligned with Rx development but how do you actually do that?
- For pharma, partnering is an essential aspect of drug and diagnostic development and commercialization, but how do you select the most appropriate partner and what happens once you've made that choice?
- If the pharma industry has developed a reputation for being 'all about the money', how can you show that your business is focused on providing the best for the patient?
- With diagnostic testing being such an essential part of personalized medicine, you'll acknowledge the link it has with laboratories, but why is that association so important?

Diaceutics is convinced that something is changing in the clinical world. We have been on top of personalized medicine since its early beginnings so we recognise the pharmaceutical industry's need to understand diagnostic development, planning and commercialization. We

are happy to share our robust insights regarding the importance and the potential impact of diagnostics in this series of articles called *Personalized Medicine: What Pharma Should Do to Get Ready*. These articles cover aspects of diagnostic commercialization such as planning, communication with stakeholders, allocating budgets for development and the importance of partnering.

We hope these articles will be a useful tool for initiating discussions, creating awareness within your team about diagnostic planning and getting you ready for a future in personalized medicine.

Establishing a Robust Diagnostic Development and Commercialization Strategy on Time

Christmas always comes as a surprise, right? All of a sudden it's 22nd December and not only have you not bought a single Christmas present for your wife/husband/kids but what's worse is you haven't got the foggiest idea what to get them. Sounds familiar? You may not celebrate Christmas itself but you can all relate to a particularly important event that everyone is well aware of and some even wildly excited about. The people around you—and you, too—know this great event needs careful preparation but year in, year out, you somehow never manage to get everything ready in time.

Now, what could this silly and possibly unseasonable example have in common with the pharmaceutical industry, where whole project management departments watch deadlines with eagle eyes, hang giant progress charts on meeting room walls and where launch dates mean the culmination of not one year, but a decade of hard work and eager expectations? Nothing, you might say. But think again, and think of diagnostic planning. Have you ever heard someone say, "We'll worry about the diagnostic when we have more robust clinical data, including the biomarker analysis read-out next spring"? Maybe you said it yourself?

Here at Diaceutics, we have delivered many projects to clients who came to us, in near panic mode, six months before an anticipated drug launch that they knew would require a companion diagnostic (CDx). However, that CDx would not be anywhere near ready for launch and the clients would have no hint of a plan for bringing a CDx to market successfully. I must admit to hating these 'firefighting projects', as we call them within Diaceutics. Not because we can't cope with the immense yet unnecessary pressure caused by having to fast track every activity—of course we can—but mainly because there is simply no way that a last minute Dx launch could be as well-designed and organized as it could have been if prepared in advance.

When the strategy is well-designed and planned a diagnostic can, and often does, play a crucial role in driving the uptake of a novel drug. If it is not the case, like with the last-minute Christmas shopping panic, you will have to go for a somewhat bland and uncreative solution just to have something to offer. The reaction of the person on the receiving end will often be polite but not particularly enthusiastic, whether that is your husband opening yet another tie, or the oncologist facing another CDx that he does not know how to use or get reimbursed for.

Based on our expertise in the field we have identified the three best practices we consider critical for developing an early and robust diagnostic development and commercialization strategy.

1. **Develop the diagnostic commercialization strategy at least 18 months before launch**
   All pharma companies know that implementing a test is time consuming but they are not aware the same is true of Dx implementation. Diagnostic commercial strategy should start at least 18 months before launch to ensure a simultaneous release with

the drug (Figure 1). During these 18 months, pharma can develop a robust strategy that aligns the Dx to the drug, determines the strategic and technical goals, prepares for engagement and management with stakeholders and plans the diagnostic lifecycle.

2. **Create a Target Test Profile**
   A Target Test Profile (TTP) is a main component of the diagnostic strategy. Similar to an architectural drawing showing the essential components of a house, a TTP is a key strategic planning document that provides a summary of a test's desired characteristics and expected technical, clinical and commercial features. To reach the required commercial development outcome, the TTP is continuously adapted along the drug development pathway. Diaceutics offers its clients a well-designed TTP to ensure they embark on a product development program that is effective and efficient, addressing all relevant clinical, technical and scientific requirements.
3. **Engage in early dialogue with third parties**
   As launching a test may take significantly more time than expected, pharmaceutical companies are advised to engage in early dialogue with third parties such as the Food and Drug Administration (FDA). Pharma can also engage with payers about issues such as test reimbursement. A test requiring a new current procedure terminology (CPT) code may take 12 to 18 months to diffuse across the payer system. Late planning can lead to frustrating, unforeseen events. Furthermore, engaging early with third party stakeholders may bring positive and beneficial surprises. The FDA approval or clearance of a test, for instance, can be accelerated when the drug and CDx are being launched at the same time.

To avoid lagging behind with the Dx strategy, pharma should start developing the commercialization strategy 18 months before launch, invest time and effort to keep track of a TTP and engage in early dialogue with third parties, as you never know how long everything will take. In parallel, drug implementation can be leveraged by aligning the robust Dx strategy to the drug development process, and it's this topic we will discuss next. For now, we will let you start planning your diagnostic strategy.

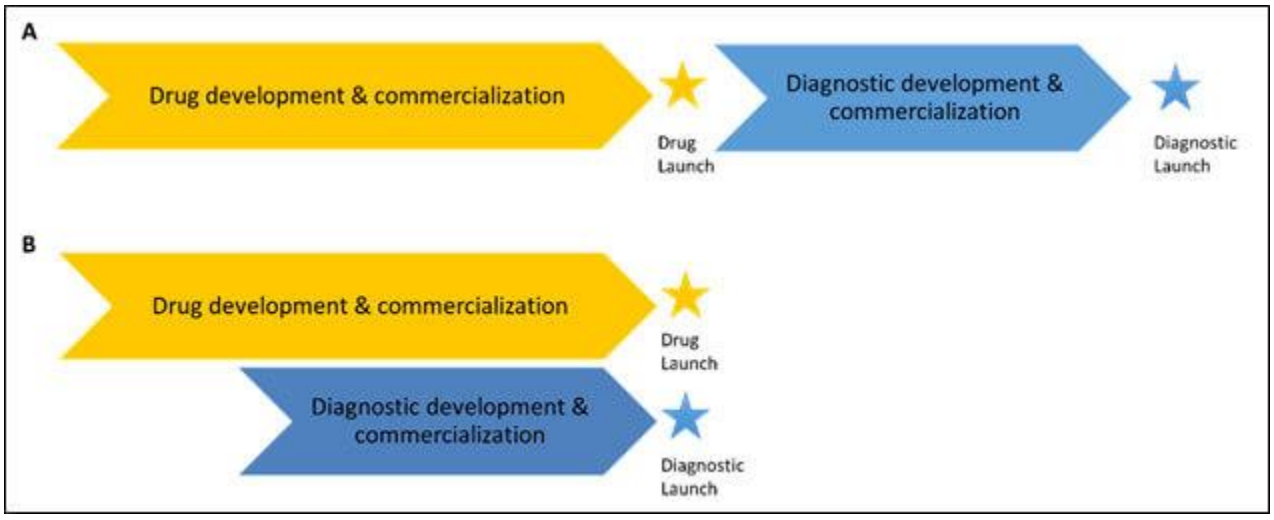

Figure 1. The importance of planning the diagnostic strategy early in time: shifting from A to B.

Integrating and Aligning the Diagnostic Strategy with the Drug Strategy

Do you know Bob, the guy who holds the budget for the project? At kick-off, he made it clear that failure was not an option and that the whole company would be dependent on this project being delivered. After that, he never turned up to a single team meeting. Suddenly, it's six months later, there is a three week slippage against the timeline and milestone three has not been met. Enough reasons for Bob to go absolutely ballistic!

I am sure you all know Bob (apologies to all the Bobs among our readers who are, most certainly, not the one I'm talking about). His behaviour is quite often encouraged in a company as it is a managerial necessity going under the name of 'delegation'. But let's define that term: delegation means that tasks are assigned to and executed by others because they can carry out those tasks equally well or even better than the representative issuing the instruction. To achieve this goal successfully, the representative provides supervision, guidance and support to the team whenever and wherever it is needed. Supervision and guidance can constitute a rather trivial reminder but how often does this essentially crucial aspect get forgotten? How often should "I have delegated this task" in effect be read as "I have renounced all responsibility for this deliverable"? Delegation is very different from negligence.

This is unfortunately a feature that is common not only between individual members of a team but also between companies who partner on a diagnostic (Dx) strategy. Having worked with nearly all top twenty pharma companies over the last ten years, Diaceutics has come across too many examples of "We don't know, our Dx partner will take care of that".

When developing a drug, the majority of pharma companies partner with Dx companies to develop a diagnostic test that will support the drug. Pharma tends to delegate the diagnostic process completely, including the aspects of supervision or guidance. The main consequence of this essentially negligent behaviour, is that the drug and the diagnostic strategies are not properly aligned which results in the test not supporting the drug and, in a worst case scenario, has a negative impact on the drug.

Based on our expertise in the field we have identified the three best practices that pharma should consider to avoid such a scenario:

1. **Review the positioning of the diagnostic in the drug development process**
   Assume that the asset will need a diagnostic test. Pharma and diagnostic companies come together to review and define how they want to position the diagnostic test to best support the drug.
2. **Develop a diagnostic strategy**
   Once the question 'How do we want to position the diagnostic test?' has been answered, pharma and diagnostic companies will develop a Dx strategy with feasible milestones. To achieve this goal, a Dx strategy has to be developed early enough in

the drug development process, as discussed in *Establishing a Robust Diagnostic Development and Commercialization Strategy on Time* (page 6).

3. **Fully integrate the Dx strategy with the drug strategy**
   While developing the Dx strategy, we highly recommend fully aligning the Dx and the drug strategy so the test and the drug can be launched simultaneously (Figure 1). Lack of coordination between drug and Dx test development can lead to the drug being launched without the diagnostic on the label. To facilitate this, pharma companies can integrate the Dx strategy into the Target Test Profile, a key strategic planning document.

Now, just think for one more moment about a new and improved Bob, and imagine him properly delegating tasks and supervising, supporting and giving guidance to his team. He knows what's happening, he's keeping a watchful eye but he trusts his team to do their job. Thinking of Bob using his best managerial talents will help us to see how pharma can only fully integrate the Dx strategy to the drug if they delegate the Dx development and commercialization to their Dx company, checking in from time to time rather than giving it total responsibility. Ensuring a good and strong partnership deal is essential and something that is discussed in *Partnering and Managing Partnerships* (page 10).

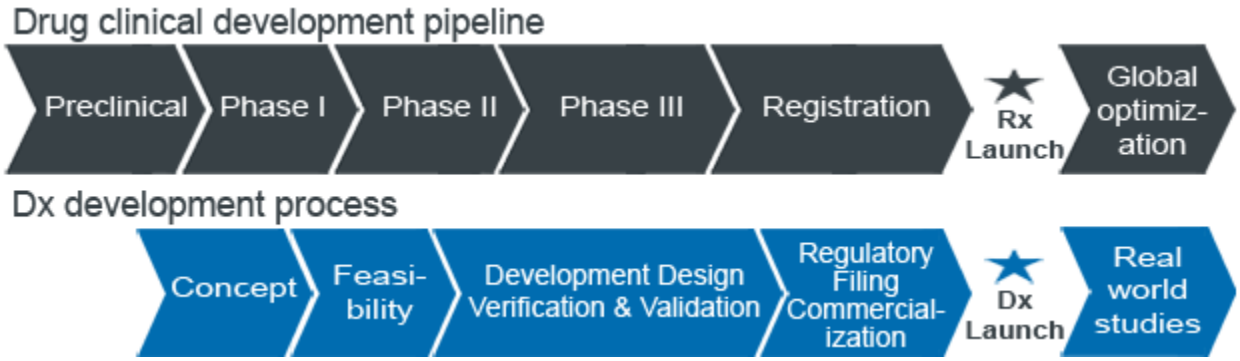

Figure 1. The diagnostic and drug strategies are aligned to each other to ensure simultaneous launch which will contribute to drug adoption.

Partnering and Managing Partnerships

Have you ever experienced a couple breaking up within your circle of friends or family? Sometimes, everyone will agree that the relationship could never have lasted, they were just too different. But the reaction might also be, "I don‘t know why she left him, he is such a nice guy." A nice guy, maybe, but not the right guy for her, it seems.

In a relationship, we are all looking for the right person to suit our different needs. For instance, one might need an adventurous partner while another wants a steady partner with no emotional swings. In a relationship, partners may fulfil all, some or not enough of our needs, as in the case of Mr Nice Guy and his finally not-so-convinced fiancée. But whatever your differences are, there are three critical success factors to make a relationship last: understand your own needs, understand your partner‘s needs and understand how to make the two fit together sufficiently well to carry you both through the good times and the bad.

A personal relationship is similar to a partnership between a pharma company and a diagnostic company. Should a pharma company partner with a well-established diagnostic company or a small and highly specialized one? As we have illustrated, there is no right answer to this question because every situation is different - companies are looking for different types of partnerships according to their needs. For instance, Eli Lilly has partnered with Primera Dx while Bayer has partnered with Ventana, two completely different diagnostic companies in terms of size and assets. So how can companies maintain a healthy pharma-diagnostic relationship‘? We have identified three relevant best practices that lay strong foundations and will hopefully avoid a business 'divorce‘ (Figure 1).

1. **Identify your needs**
   Are we lacking any specific expertise? How many partnerships do we want to engage in? Do we want to partner with different companies or with the same company for both the development and the commercialization process?
2. **Select and engage with a partner**
   Based on the pharmaceutical company’s needs, a shortlist of potential partners should be drawn up. The company will select the final partner(s) by giving weight to additional criteria such as development capability, medical platforms, clinical application and commercial experience.
3. **Manage the partnership**
   Managing the partnership over the long run is essential to keeping a coordinated dialogue. We would advise that companies delegate rather than leave full responsibility to the partner, as we discuss in *Integrating and Aligning the Diagnostic Strategy with the Drug Strategy* (page 8).

As you will have noticed by now, there is no single winning partnering model that every company should follow. However, the three best practices we have mentioned are vital to keep in mind when engaging with a partner. Based on our experience in the field of personalized medicine, managing the partnership is the practice most often forgotten. Pharma tends to assume that the partner will do everything as it has the expertise. However,

forgetting to manage the partnership and leaving one partner—often the diagnostic company—with full responsibility may lead to a break up, especially if the needs of a company change during the process or there is any miscommunication.

In conclusion, after selecting your ideal partner, make sure you keep working on the relationship. Isn‘t that also good advice for you and your own special someone?

Figure 1. The steps pharmaceutical companies should take to ensure a long-term partnership.

The Shift Towards Patient Centricity

Sometimes you overthink so much that you forget the essence and core of the issue and ask yourself, “What was it all about again?” The other day, I experienced this uncomfortable feeling when discussing with my partner how to organize the perfect birthday party for our daughter. While I thought we should go bowling, my partner tried to convince me to have a big traditional birthday party, with pass-the-parcel and other fun games. The discussion went on for some time until we heard our daughter cry, “I don’t like bowling and I don’t want to play silly games. I want to invite all my friends home and dress up”. Maybe we should have asked her first? It made me realise that the one person the party was for was not even getting a choice in what she wanted.

Pharmaceutical companies might also have recently asked themselves, “What is it all about?” while developing their strategy. The answer is, it’s all about the patient! Pharma indeed starts to consider and take into account the patient’s voice. Does a patient really want to be prescribed a certain drug that can cause significant side effects? Imagine an 85 year-old woman, slightly confused because of symptoms of dementia, who needs to be tested for Alzheimer’s disease by having a spinal tap. At her age, and in her condition, does she really want this painful procedure? Isn’t there an alternative? Different companies such as AstraZeneca, Pfizer and Sanofi have developed specific corporate roles to consider these scenarios and encourage patient centricity within their business (Figure 1). We have identified the three essential best practices that can help large pharmaceutical companies integrate patient centricity into their strategy.

1. **Improve the patient pathway**
   When a patient gets sick, he will be prescribed a drug to cure him. But treating a patient is not only about the drug and there are many factors on the patient pathway influencing his quality of health care, such as getting a diagnostic test, the follow-up procedures after treatment and reimbursement for the diagnostic test and the drug. By reviewing the whole patient pathway, pharma can better understand the patient’s experience and identify unmet needs to address in order to improve health care quality.
2. **Listen to the patient’s voice**
   Without listening to the patient’s voice, pharma will not be able to achieve patient centricity. In an Expert Insight, Gwen Darien, a cancer survivor, confirms this statement by describing the patient as a multi-dimensional person who should be engaged actively in the discussions. She says, “To develop this [personalized medicine treatment approach], we need to understand both the individual and the greater community of which she is a part. We must engage patient voices in open, transparent discussions about issues that are important to them personally.”
3. **Integrate patient centricity into the company’s strategy**
   Integrating patient centricity is a feasible task and will likely not require change to the whole company strategy. Pharma companies can develop either a small separate department to deal with everything related to patient centricity or appoint a ‘leader of patient centricity’ who will advise different teams on the topic.

A shift towards patient centricity, or putting the patient at the centre of the discussion, is happening at the moment. Pharmaceutical companies could integrate this concept at the heart of their business and scientific development in order to improve a patient's outcome. In the end, it is all about the patient!

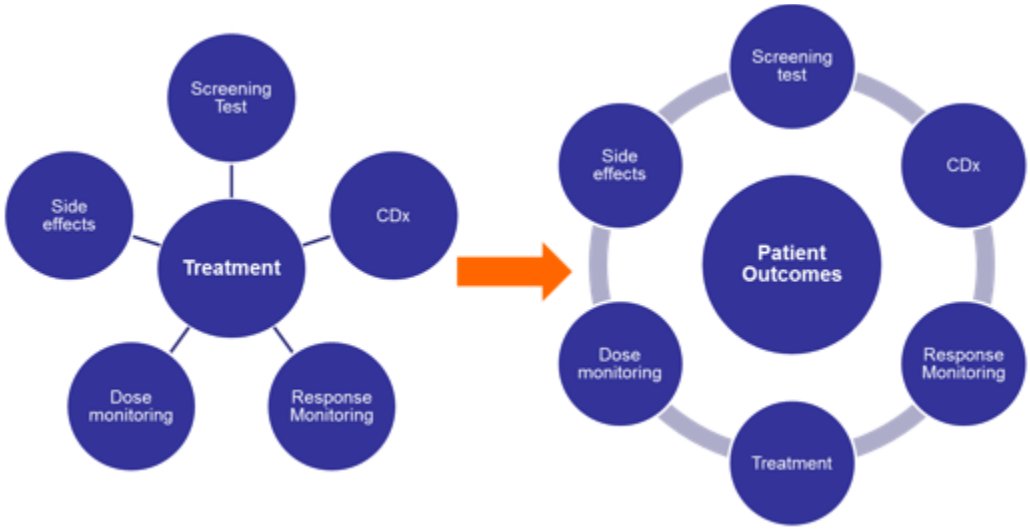

Figure 1. An illustration, from a pharmaceutical perspective, of the shift from a treatment-centred approach towards a patient-centred one.

Pharma Communication and Education for Stakeholders

Do your grandparents surf the internet to read the latest news, send emails to organize a brunch or chat with friends on their smart phones? Probably not, because why should they? Why would they replace their newspaper, their post and their landline for internet-based services when these still work and they're used to them? Younger generations have already replaced traditional ways of communicating because they appreciate the huge benefits of new technology—it is easier, faster and gives many more opportunities. If older people live an internet-free life, untroubled by too many emails, perhaps the main reason is that the positive benefits of the internet and a digital lifestyle have never been explained using a language they understand.

As with mobile technology, the pharmaceutical industry evolves really fast. New drugs accompanied by new diagnostic tests are regularly being launched. In the same way that your grandparents may find it difficult to understand technology that moves so quickly, various stakeholders can encounter difficulties keeping track of the many changes in the pharmaceutical industry. Physicians, for instance, stick to the drug which has been on the market for a long time rather than adopting the newest drug and diagnostic test as they do not understand them well. Physicians will only adopt the newest drug and test if pharmaceutical companies take the time and the effort to communicate with them in a language they understand.

A study showed that most physicians do not feel comfortable using genomic testing, which is a relatively new and promising technique, because they do not understand the basics of the test and experience difficulties talking about it with patients[1]. In addition to appreciating the benefits of a new diagnostic test, physicians need to know about other aspects, such as whether the test will be reimbursed, privacy issues and how long it will take to get the results.

Together with strategic partner CAHG, Diaceutics has identified three best practices for education and communication with stakeholders that pharmaceutical companies should consider to ensure drug and test adoption.

1. **Educate physicians**
   Physicians are at the centre of the communication flow as they have direct contact with pharmaceutical companies, laboratories and patients. It is essential, therefore, to provide physicians with a clear message and the knowledge they need to confidently discuss a new drug and diagnostic test recently launched on the market, otherwise the drug and test will not get adopted.
2. **Educate patients**
   The patient will be educated partly by the physician, which highlights the importance of the best practice already mentioned, and partly by looking into their own health care options. Providing additional information to the patient, in the form of a website or leaflets that are easy to understand, will make the patient confident about the treatment or diagnostic test he or she will be getting.

3. **Educate stakeholders according to their 'needs'**
   Pharma should make sure it provides the information on a new drug or test to all stakeholders according to their needs (Figure 1). For instance, when launching a new diagnostic test, the sales force needs to understand the added value of the new test over the older one, while the physician can be informed on which drug needs to be prescribed following the test results. Simple communications with a clear message about the drug and the test will help stakeholders feel comfortable talking about the drug and the diagnostic test.

It can take many of us a long time to adapt to new ways and ideas, but a transition can be eased with simple and clear instructions. The communication between pharma and physicians is particularly important as physicians are at the centre of the personalized medicine communication flow. Ensuring good education of the physician will help drive adoption of the drug or diagnostic test. Watch out for an email from granny soon, telling you all about her visit to the doctor.

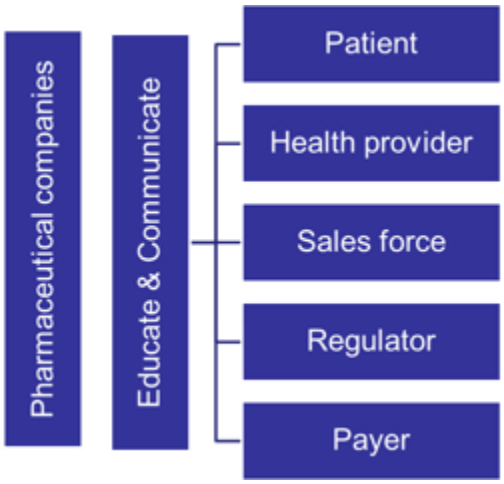

Figure 1. To ensure proper market implementation of a new drug and diagnostic test, it is essential that pharmaceutical companies educate and communicate with all stakeholders according to their needs.

References

1. Market research performed by CAHG in 2011.

Funding a Diagnostic Test at Launch to Ensure Test Adoption

Uber is a young company that, as you probably know, offers taxi services through a smartphone application linked to the customer's credit card. Traditional taxi services consider Uber as a competitive threat due to its low fares and special customer services, which range from offering a bottle of water and mints to easy-to-use payment through the app. The most interesting thing about Uber is its implementation strategy. It all started in San Francisco, USA, and the company quickly expanded to other American cities. The founders were not scared to think big and challenged themselves to establish Uber worldwide. To achieve this goal, Uber invests in friend-to-friend commercialization to acquire new customers. Each time an Uber user invites a non-user to sign up and use the app for a ride, the Uber customer gets free credit on their account and the new customer gets the first ride for free. And this is happening worldwide… What a huge financial investment!

In the field of personalized medicine, a drug is launched together with a diagnostic test and the main challenge to ensure test adoption is consistently reimbursement. So, getting back to the Uber implementation strategy, how does this example relate to the pharmaceutical industry and, in particular, to the field of personalized medicine? In order to drive test adoption, pharma must first 'socialize' laboratories by offering the new test for free at launch for a certain period of time, in the same way that Uber connects with potential customers by offering them their first Uber ride for free, thereby driving product adoption. Diaceutics has noticed that an increasing number of pharma companies fund the diagnostic test at launch in conjunction with three best practices (Figure 1):

1. **Fund the diagnostic test at launch where possible**
   Funding a new diagnostic test is a great way to drive test adoption in the market. Pharma should plan and adapt for each country as they all differ in terms of their regulatory process. For instance, in Germany, funding a diagnostic test at launch is not allowed.
2. **Fund the diagnostic test according to market requirements**
   Reimbursement of a diagnostic test varies across countries, particularly in Europe, where every country has a different way of covering the costs. Due to the complexity, pharmaceutical companies need to understand the individual European markets. For instance, Italy's reimbursement system is based on local catalogues and therefore some variation is seen between regions, whereas France has a national system for oncology which is controlled by the French National Cancer Institute (INCa).
3. **Ensure careful exit of diagnostic test funding**
   While subsidizing a diagnostic test at launch is a good strategy, pharma should also carefully plan the exit by developing a robust plan. In fact, if pharma suddenly stops subsidizing testing when no alternative reimbursement is in place, laboratories are likely to stop using the test.

Finally, Diaceutics believes that funding a diagnostic test at launch is a great solution to drive adoption because it addresses the time gap that exists before test reimbursement is implemented. In addition, this opens up a way to educate and communicate to laboratories on the availability of the newest test. Uber offering a free ride to a new customer is like pharma subsidizing a new diagnostic test at launch. While Uber wants to gain more customers, what is at the end of pharma's journey? Driving drug adoption to deliver personalized medicine!

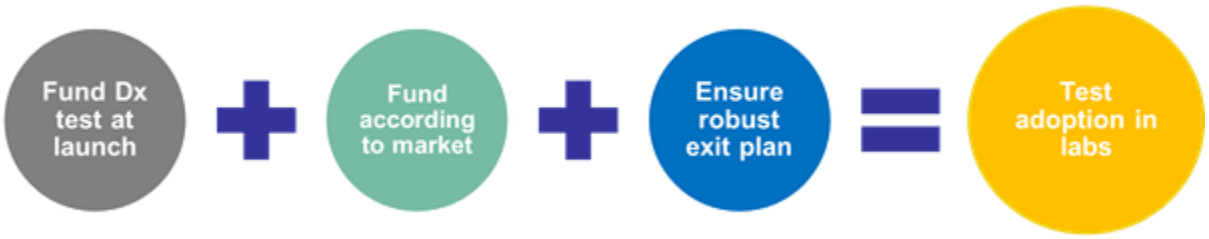

Figure 1. To ensure adoption of a new diagnostic test, pharmaceutical companies are encouraged to fund the test at launch according to market requirements and to develop a robust exit plan.

Engaging with Laboratories

Have you ever met someone who stopped running a marathon after 37km because he got bored? Have you ever heard of someone building a house and planning to add the roof the following year? Would you ever consider reading a thriller without finding out 'whodunnit' in the final chapter?

You would think that forgetting to run the last mile doesn't really happen often and would be a very silly thing to do. You might not recognize yourself or anyone you know from these examples. However, pharmaceutical companies do actually forget to run that last mile—they forget to engage with laboratories.

Diaceutics has come across many examples of pharmaceutical companies planning in great detail and rolling out their robust drug and diagnostic development and commercialization strategies. But when they are nearly at the end of the process they forget to engage with laboratories to communicate the benefits of their precious newly-launched diagnostic test.

"Labs were traditionally the forgotten stakeholders", says Maria Fe Paz of Labceutics, a division of Diaceutics that aims to enable efficient testing in laboratories. The main reason why pharma forgets to engage with laboratories is probably because labs used to play a smaller role before the arrival of personalized medicine compared with today. Maria thinks that laboratories today play a key role in performing the diagnostic tests because the results they provide will guide the choice of the therapy the patient will receive. She explains, "In this rapidly evolving landscape of personalized medicine, laboratories play a critical role moving forward. Upon this realization, the other stakeholders, including pharma and diagnostic companies, start to leverage laboratories' specialized expertise for a faster and more successful implementation of companion diagnostics, through more interconnected collaborations."

Diaceutics has identified three best practices to ensure that pharma engages with laboratories. These practices are based on Labceutics' expertise that aligns the efforts of pharma and diagnostic companies to achieve efficient diagnostic testing in laboratories:

1. **Define a lab footprint**
   Defining the lab footprint before the test launch is essential for having the test ready in all territories. In the USA, the two companies Quest and LabCorp provide most of the laboratory services. However, in Europe and Japan, for instance, the laboratory sector is highly fragmented. Therefore, pharma should ensure that the right number of laboratories are ready to run the test from the day of launch.
2. **Engage and leverage laboratories**
   Multiple hidden hurdles are faced when introducing a new test to the market, such as the test set-up, the costs of test implementation and selection of the test method/platform. Pharma should engage with pathologists and labs to understand their needs and any potential hurdles for the test. Finally, leveraging laboratories will drive test and drug adoption.
3. **Provide communication about the test and its protocol**
   An additional factor to ensure test adoption is to provide enough information about the

test and the protocol. Communication between pharma and its stakeholders has been discussed in more detail in *Pharma Communication and Education for Stakeholders* (page 14).

Laboratories and pathologists are often overlooked by pharma and we can see that they are the forgotten stakeholders. Engaging with laboratories will drive test adoption and, if we are talking about a companion diagnostic test, it will drive drug adoption as well. In summary, always run the last mile and think of the laboratories as one of your key stakeholders. When you do cross that finishing line, you may have won first prize.

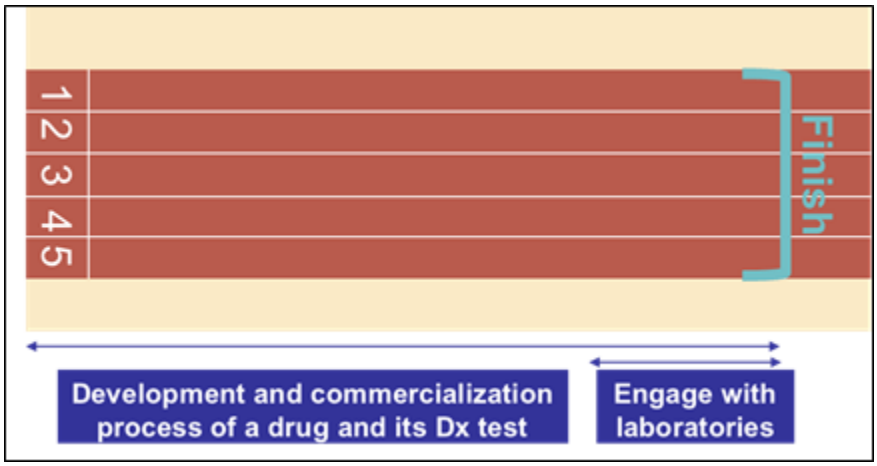

Figure 1. When launching a new Dx test, engaging with laboratories is like going the last mile during a marathon. Don't forget the laboratories - an important stakeholder.

Ensure Diverse Internal Capabilities in a Personalized Medicine Pharma Company

When you are watching a soccer game at the European Championships or the Women's World Cup, there are often one or two players who immediately catch your eye as they play amazingly well. These players seem to be individually responsible for the final score and the victory. However, team sports - and the clue is in the name - are all about the team performance and every player plays a part in its success. In fact all the players have skills and contribute to the team with their specific expertise, for instance, as the striker or goalkeeper. If ever one of the eleven players is weaker or even has to leave the pitch, let's say it is the defender, then the team will find it harder to win the game even though the strikers are still scoring goals. Isn't it really straightforward?

Being part of a company is like playing a team sport, where every member or player is necessary and contributes his specific skills and expertise. Over the years, employees of pharma companies have acquired significant expertise in drug development and commercialization. Today, pharma invests in personalized medicine, an area where diagnostic tests play an important role. To play this personalized medicine game, pharma should invest in the diagnostic expertise of the company by building internal capabilities in the field. How can pharma buy its own version of Manual Neuer in goal, or the Robin van Persie of diagnostics to keep scoring goals, or an equivalent of the three times Olympic women's soccer gold medallist, Christie Rampone? To address the challenges of building internal capabilities, Diaceutics has identified the following three best practices to help you win in the arena of personalized medicine.

1. **Ensure the team has diagnostics commercialization experience**
   Whilst pharma has a track record of hiring people with diagnostic development skills, diagnostic commercial skills are often neglected or are assumed to be provided by the diagnostic partner. To ensure a team has relevant diagnostic commercialization experience, pharma can either recruit people with relevant experience or educate internal teams across functions. Some pharma companies go one step further and become experts in diagnostics, such as Roche, which has developed its own in-house diagnostic division. This topic is discussed in more detail in the Expert Insight, *Drug/Diagnostics Partnering Deals Flow: A Changing Landscape*[1].
2. **Executives with integrated drug and diagnostics commercial skills**
   In the personalized medicine space, the ideal commercial leader needs to have had both pharma and diagnostic commercialization experience. Excellence in personalized medicine is about the integration of commercial plans, not about running diagnostic and therapy commercialization in parallel (Figure 1). For instance, medical sales representatives are having to educate physicians about the therapy as well as the test, a type of integrated approach that represents a shift in planning, productivity and communication[2].
3. **Skills to measure diagnostics**
   Today's soccer coaches measure everything from fitness and performance to team formations. They measure to enable continuous live adjustments to the game as it happens. Pharma is familiar with the measurements associated with therapy

commercialization and organizational investment. This same discipline needs to be part of personalized medicine teams as joint drug and diagnostic commercial teams. Here are a few examples where skills to measure the diagnostic metrics are required to underpin the therapy metrics:

- LabMapping[3] to measure which labs serve which physicians for which test
- 'Propensity to Prescribe', which measures the number of positive tests that convert into treatment decisions
- Return on investment of different tactics to drive test adoption.

In summary, pharma companies need to develop the right internal capabilities, using the most valuable resources—people—to work on both the drug and the diagnostic development and commercialization processes. However, not all expertise needs to be in-house and pharma companies are encouraged to partner in order to fill in the gaps. Partnering with a technology company to develop an assay or leveraging another company's expertise in measuring the laboratory and testing landscape could build strength across the organization.

In 2015, New York honored the US women's national soccer team's victory at the 2015 World Cup with a ticker tape parade. Fans lined the Manhattan streets to show their appreciation for the players. The final against Japan was a masterful display of a team at the top of its game. Personalized medicine commercial teams of today (the joint drug and diagnostic commercial teams) are, for the most part, still on a learning curve but the skills required to deliver superior return on personalized medicine investments are no longer a mystery. Which company will get on top of its game and win the next gold medal?

Figure 1. Personalized medicine teams from a pharma company need to ensure they have integrated drug and diagnostic commercialization skills across all levels of an organization.

References

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Budget Allocation for Diagnostic Development & Commercialization

Have you ever dreamed of buying a Rolls Royce? Driving one seems like an effortless pleasure and owning one must make you feel like the ‘king of road’. Although Rolls Royce promises to 'keep your investment in perfect condition’, buying a luxurious and graceful car like this is a major financial investment. Perhaps you should be practical and just stick with Volkswagen, a brand that offers perfectly affordable cars which last a long time. Then again, you realise that owning a Volkswagen does not shout ‘king of the road’. So you start investigating the different ways to get that Rolls Royce even though you can’t afford it. You surf car websites to find a Rolls Royce with a Volkswagen price tag… and then you realise there is no alternative: only by spending a large sum of money on a Rolls Royce will show that you are a leader.

Similarly, pharma companies invest in personalized medicine because they want to become leaders in the field. They are likely to be aware of the main ingredients necessary to achieve this leading position, such as aligning the diagnostic strategy to the drug strategy, partnering with the right diagnostic company, engaging with laboratories, etc. However, this diagnostic development and commercialization process requires a large investment and pharma is sometimes reluctant to do this (Figure 1), hoping that allocating a Volkswagen budget will bring them the Rolls Royce prestige. Based on ten years of experience in the field of personalized medicine, Diaceutics has identified three best practices that are essential for the diagnostic development and commercialization process.

1. **Complete an early financial impact assessment**
   Pharma should complete an early financial impact assessment to determine the budget to spend on pre-launch and launch activities. Completing this assessment gives a company an estimation of the financial effect of the strategy and will eventually make team members aware of the value of investing in a diagnostic strategy.
2. **Allocate sufficient budget**
   Pharma should remember the Volkswagen versus Rolls Royce example when allocating a budget. In fact, the budget allocated for investment in the diagnostic development and commercialization process should be sufficient to achieve a position close to the leader in the personalized medicine field.
3. **Invest in diagnostic adoption drivers**
   Even the best drug and most accurate test will not be adopted on its own as nothing sells itself. Newly-launched drugs and tests need a commercialization strategy for adoption. We have already identified different drivers that are worth investing in, such as communicating with and educating physicians and working with laboratories, and discussed these earlier.

In conclusion, pharma should be aware that in order to compete with the leaders in personalized medicine they will have to allocate ample budgets for the diagnostic development and commercialization process. It may be just the diagnostic division of a pharma company that is investing in diagnostics but the whole company has to realise the

importance of the diagnostic strategy in driving personalized medicine. Investing in only a part of a Rolls Royce, let's say the motor, is unlikely to make you a leader in the field—you definitely need the whole car to take you there.

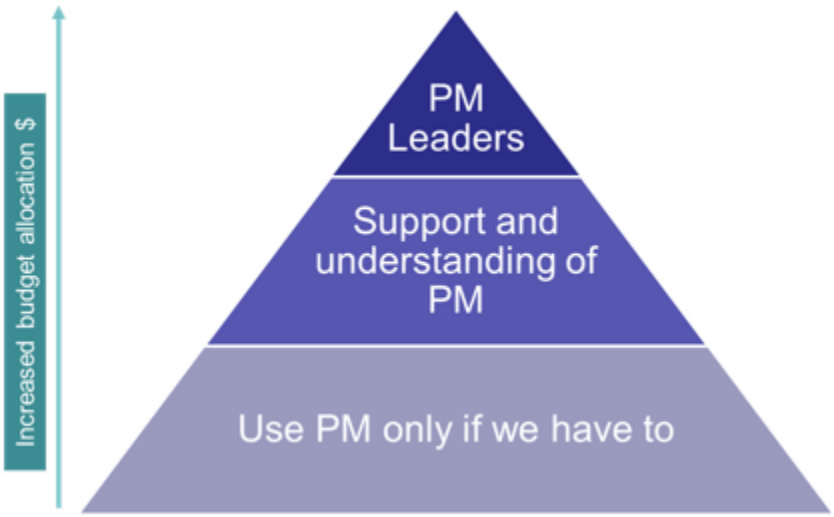

Figure 1. Pharma should allocate budgets according to their strategy. Sufficient budget will be needed to become a leader in personalized medicine (PM).