DECEMBER 2019

Prepared by: Nick Hicks, Commutateur Advocacy Communications

INTRODUCTION

This is the transcript from a recorded webinar, "Searching for the right patient engagement path in medical devices", delivered by Nick Hicks of Commutateur Advocacy Communications on December 3rd 2019 to an audience of life sciences professionals.

Speakers: Paul Copcutt, faciliator and Nick Hicks.

PC: Today's webinar is being recorded, so we will be making that available to you after the webinar. Welcome to the webinar on practical tips for building a patient engagement path for medical devices brought to you by Commutateur Advocacy Communications. The webinar will be starting in just a second. If you have any questions, we've had some questions sent in, but if you have any questions, we do have a chat facility on the webinar, so if you just hold it down to the bottom of your screen and click on the chat. If you have any comments or questions, you can put those into the chat. If you do have a question, it'd be helpful if you just put a capital Q in front of it so that we can quickly find it in the chat as there tends to be a lot of conversation in that box. So that would be great. What I'd like to do is just introduce you to our presenter, Nick Hicks.

Nick Hicks is the director of Commutateur Advocacy Communications, a patient engagement consultancy who supports advocacy leaders within the life sciences to implement their patient engagement strategy through delivering genuine benefits to both the company and the patient. And I'm going to hand it over to Nick.

GETTING ENGINEERS TO MEET PATIENTS

NH: Thank you, Paul. And hello everybody and welcome to today's webinar.
My name is Nick Hicks and without any further ado, I want to go straight into an editorial which came from Medical Devices online from January last year. It talks about sending engineers into the operating room to make better devices.

The whole objective of this webinar is to actually understand how the patient voice can be used to make better medical devices. This webinar is going to be looking at the best practice, techniques and learnings from the Pharma industry. So perhaps we could actually say, “to make better devices, send your engineers to speak to patients”. Why? Well, certainly earlier, broader and deeper engagement of patients offers a huge opportunity for companies to optimize the commercial performance of a product or service by allowing the patients a voice and allowing the patients to have a say right from the start.

QUICK READING SUMMARY

Build the institutional relationship between the medical device company and the patient group based on value and trust.

Identify and align on common issues of high unmet concern.

Work transparently at all times, communicate consistently and often.

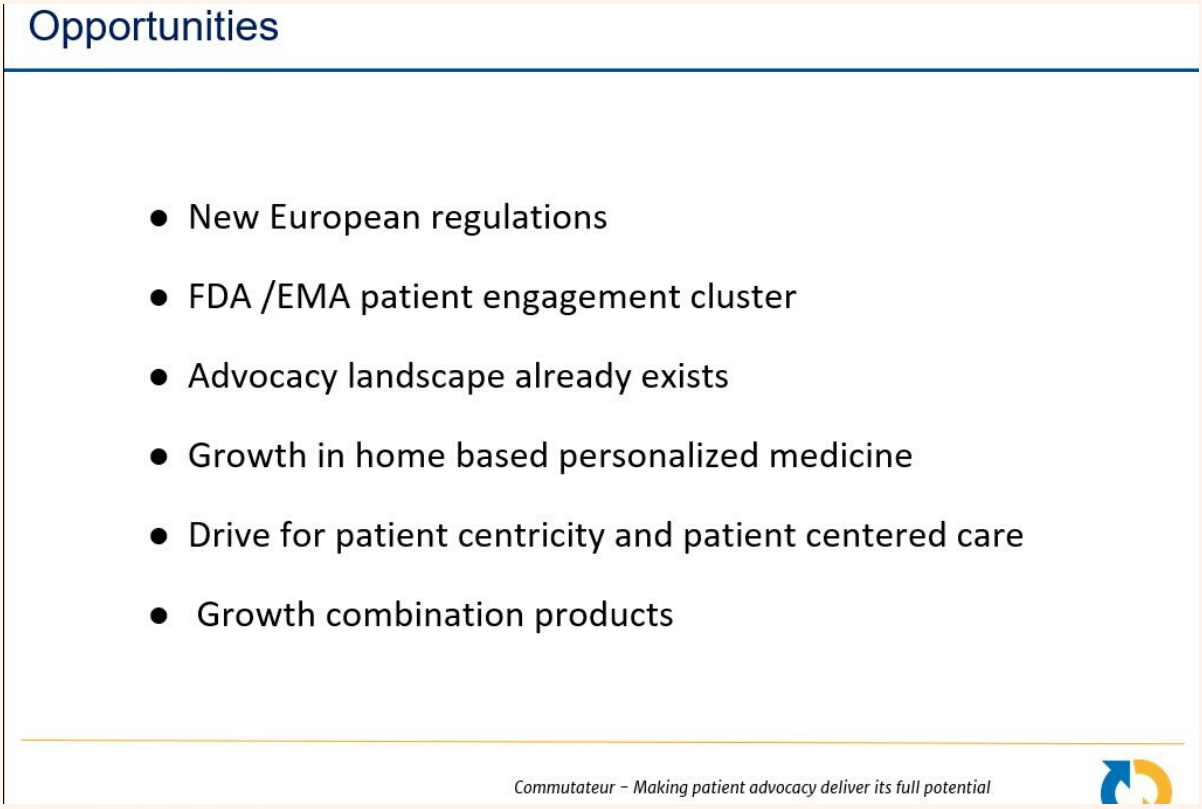
Take a long term view and not on the short term bottom line.

Build in an engagement strategy around the capacity needs of the patient group.

Definitions matter; identify how best to align company plan with patient advocacy, patient engagement and patient experience.

OPPORTUNITIES

N**H:** Now the traditional worlds of Pharma and MedTech are continuing to converge. Previously they were always traditionally very separate. Now with Pharma expertise nowadays being used to help medical device companies conduct clinical trials, there is an increasing number of combination products and the ongoing move towards a patient-centric approach and personalized one-to-one care. Now I see that the opportunities for more in depth working with patient groups and advocates is a combination of factors.



The new medical device regulations coming in from 2020 requiring companies to provide more robust data, looking at patient preference, risk benefit assessments are what the regulators want - patient involvement in medical devices. Also, the landscape already exists because in a lot of the areas where there is market growth there is a combination of products seen, for example prostate cancer, cardiovascular disease, colon rectal cancer, diabetic neuropathy, obesity and diabetes. There is a very, very strong advocacy following there, which medical devices can easily jump onto. A lot of the hard work has been done. The benefits for life sciences companies, is making the inclusion of the patient voice best practice for product development.

Health Authorities are asking patients to contribute to product approval discussions and all of the major HTA authorities in Europe, whether it's NICE in the UK, HAS in France, GB-A in Germany, and TLV in Sweden for example. All of them have dedicated patient pathways for the patient voice in access of discussions. Now these activities though are principally being driven through the patient groups and the patient advocates, target audiences who I think, the medical device community has traditionally not really engaged with to such a far extent.

NH: But as I say, this I think is now changing. Now there are four types of stakeholder groups who are relevant here, and it's worth remembering again, that the market growth in a lot of the key combination areas is already well developed or already has strong patient advocacy groups and patient advocates in these areas. Now we're going to be talking today about the patient group, the patient advocate, EU groups, and the individual patient.

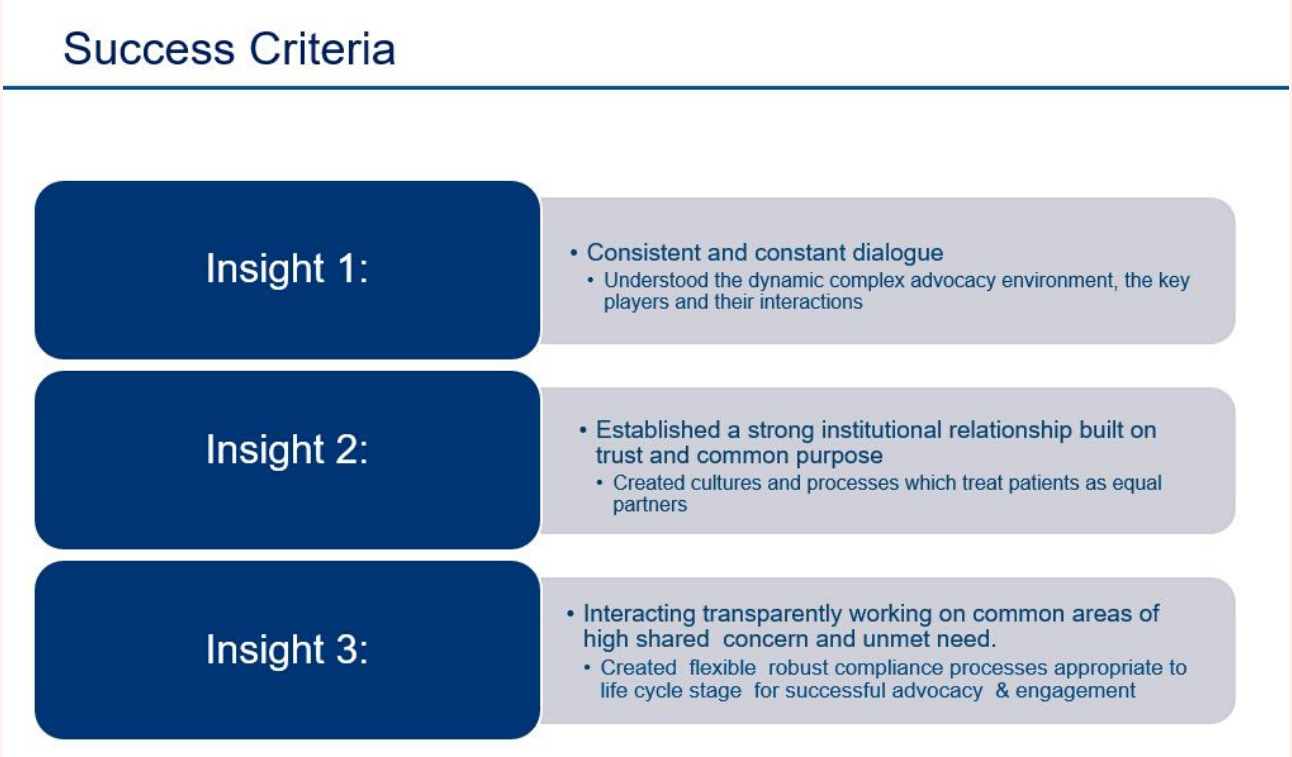
Now definitions really, really do matter and pharma have understood this and have divided patient-centricity into three distinct types. The first one is patient advocacy. And this is the traditional role of the patient groups and advocates. And it's used to shape the environment. For example, disease awareness campaigns. Now advocacy is well-defined, and it is the traditional role but also it is used very effectively as part of an overall market access that can campaign for example in raising awareness about lack of diagnosis or lack of availability of certain key medicines. So, disease awareness is patient advocacy.

Now the second one is patient experience. Now this involves meaningful interactions with patients and caregivers and where appropriate to understand their emotions, their needs and their decisions along the patient journey. The patient journey is now becoming very well understood and successful strategies have clearly identified and split down the patient experience into a very, very detailed understanding.

Lastly is patient engagement. Now this includes discussions around topics such as their potential for treatments and their diagnosis. And this is a deliberately busy slide because it just shows you the range of patient involvement, the various stages and tactics which patient involvement can be involved in within medicines R and D. I think it's fair to say that pharma probably has a lead over medical devices here, which traditionally have been more focused on post-marketing surveillance and user testing.

And yet one area of opportunity which I see, just in discussing with patient groups at some of the key European events, is that they have a real interest in outreaching with medical device companies, especially in the early stage of development. Now, patient engagement does not have a common definition unfortunately. And you'll see that different companies, different organizations have a different term for it. And it's because it comes from multiple, it comes from multiple perspectives. And these are individual, relational and organizational. So really what companies are doing, they're developing a definition of patient engagement that works for them.

THREE SUCCESS CRITERIA



NH: Now, success criteria. The first one is mapping the advocacy landscape to know where to start because patient advocacy is a structured and very integrated dynamic process and the key advocacy activities do follow a predictable pattern. And the most effective advocacy programs will evolve over time to reflect the evolution of the disease state and the life cycle stage of a company's product. Now this understanding allows consistent and constant dialogue on the subjects that matter most. And successful companies see advocacy and engagement as long-term initiatives, not a toe in the water lasting a couple of months and then stopping. You can't go in and out.

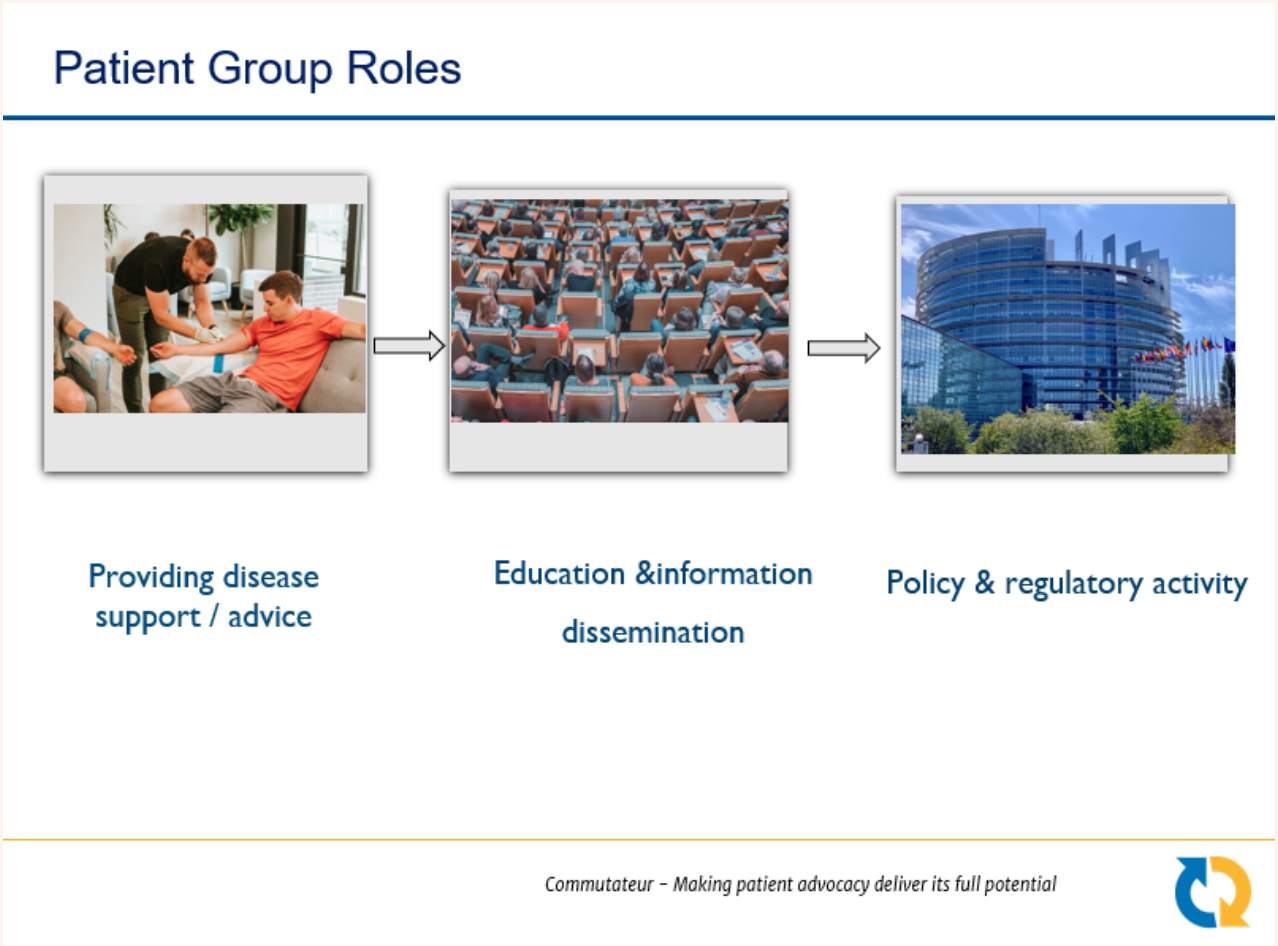
Once you're in, you've got to stay in, and they build a topographical map of the advocacy landscape. Now this advocacy landscape is complex, and it comprises a multitude of stakeholders and it is dynamic as I say. So you have to understand the key decision makers, their interactions and positions on the key topics because this will shape your strategy. Without doing this, initial due diligence work, any advocacy or engagement activities will not be as effective as they could have been. You can't have effective patient engagement without patient advocacy. Now, successful strategies have identified both the potential influences and detractors, and it is important to also identify the people who may have negative opinions against a particular position or service.

And these groups will be used at different times of the life cycle. So just let's have a look at some of these patient groups and advocates and go into a little bit more information about who they are now.

THREE SUCCESS CRITERIA CONT.

NH: Patient group roles. Successful strategies have identified the role and the position of the patient group in three areas. Now, patient groups have really been around since the 1930s with the creation of Alcoholics Anonymous, though it doesn't really follow the criteria nowadays for a patient group. We can trace back the modern-day advocacy movement to the early 1980s and the AIDS crisis. Now, what these people have done in the companies, is they've understood the various roles the patient groups play in providing disease support and patient advice. And patient organizations are really involved in making sure that new treatment innovations are available and offer significant benefits to patients.

Now, patients. They've fought a long time for a seat at the table and now they are very, very well recognized amongst the regulatory authorities as providing very important insight and patient organizations have taken it upon themselves to train patients on how to have input into the science of drug development.



FOUR IMPORTANT EUROPEAN INITIATIVES

NH: So, what I'm going to do now is just to show you four important European patient initiatives. Useful if you are considering looking at patient engagement now. The first one is called PARADIGM. This is a public private partnership and it's co-led by a very significant European group called the European Patient Forum and EFPIA, the European pharmaceutical trade body. The objective is to develop much needed processes and tools in three decision making areas:

- research priority setting
- design of clinical trials
- early dialogue.

EUPATI is more of a training multi-stakeholder program, again hosted by the EPF and it focuses on training patient advocates, allowing them to participate in clinical R and D.

The other is the Patient Focused Medicine Development. It aims to improve understanding, and how to get patients involved far more effectively in the design of new treatments. The last one is the Innovative Medicines Initiative, which is a public private partnership. This one is aiming to speed up the access of newly developed treatments.

These are all open. I would suggest you have a look at some of these and I know the patient groups are interested in reaching out with medical device companies. Now going back then to the patient role and lastly patients are very closely involved in policy and regulatory activity. All of the major, regulatory committees in the EMA have patient strong patient representation.

PATIENT GROUPS AND PATIENT ADVOCATES – WHAT'S DIFFERENT?

NH: Now the patient advocates. This is a fairly new phenomenon and, again, Pharma have had long-established relationships with advocacy organizations. There's a growing wave of patients, individual ones who want to get involved and want to speak up and to provide insights to help the industry identify opportunities for both the patient experience and care.

But companies again, have clearly identified the different patient advocate roles and are using them very effectively Patient advocates can use their influence and experience in new ways, going beyond traditional ambassador roles, which they have, and they can serve on advisor boards, speaking at industry events and co-authoring research papers. More and more are doing this now, and as this going beyond this ambassador role is likely to grow, more companies are discovering the information shared by trusted patient advocates is an incredibly powerful way to reach deeper into patient communities and address some of the key issues which are of concern to them.

NH: The consistent and constant dialogue creates a strong institutional relationship. And this is probably the most important factor in determining the success of an initiative. Don't try and go too fast or too complex without having built this relationship up. Put a focus on building respectful, honest, and trusting relationships. And when you've got that as a foundation, so much is possible. Transparency underpins everything and that is vital and why you need to be very clear from the start with what you want to do with the patient group. Changing objectives midstream is not going to work very well and you have to understand that the message has to be broader than the bottom line. You have to see the bigger picture as well, not just the market share.

HOW TO SELECT A PARTNERSHIP PROJECT

NH: Now, online strategies are also a significant factor in successful advocacy and engagement. They inspire innovation, they inspire engagement of patients, but it's a subject all unto itself. So, I won't be going into that today. Now the criteria for patient selection is very important before partnering with a patient group or advocate and always be mindful of these five general points.

Working in patient communication is time consuming and there is always the possibility that it could be open to misinterpretation. That is why the vital consistency of communication may be a challenge, especially in situations where you may have multiple touch points within the company. Therefore, always ensure that you bring in compliance at least six months before any advocacy initiative. Now, specifically the institutional relationship between a company and a patient group is probably the biggest influence in creating a successful outcome.

And this does not take place overnight. And the best way to do this is to ensure you focus on common areas of high concern. And very often, well, what you have to do is for each patient group with which you wish to partner, you have to select the best group. And the best way to do that is to identify pre-selected criteria which you can tick off, which correspond to the attributes you need that particular patient group to possess before you start. Now you need to identify the best approaches that cement the relationship in the very early stages. So, it's important to start small and to work up.

Criteria for Selecting Partnership Opportunities

- Balance between company and patient group output
- Compliance
- Contact points within the company (multiple!)
- Potential negative perception e.g. media
- Internal resource allocation

Commutateur – Making patient advocacy deliver its full potential

USE A SIMPLE PLANNING TOOL

NH: What are the simple ways to identify the common areas of a shared interest? It's not rocket science. You identify the market access hurdles and you identify the market access stakeholders. And I know there are some specific or unique access challenges to medical devices, for example, the notable authorities.

But nonetheless, this type of very simplified planning approach can be very useful because what you then do is that you then identify the appropriate advocacy tools, which can be used at a European and a national and local level. And the types of advocacy engagement tools which have been and are very successful can address that equal access to treatments or services, disease education, basic research gaps and health policy.

WHAT APPROACHES WORK

NH: For example. Now the approaches that work, there's three main ones. The keyword here is “co-creation”, and advisory boards are a very successful way of identifying and working with new advocates and new patient groups in the early stages. And it's important to invite both antagonists and protagonists to the event. Now, hosting a patient summit is another simple, way to gather diverse opinions on subjects which patient groups wish to be informed about.

And for example, here I would see that may be an idea to run something on privacy concerns surrounding data capture by medical devices. Now one point which is often overlooked is the patient group lifecycle. Patient groups do have a lifecycle, and this can influence the type of outreach strategy which you use in the key, commercial areas, which medical devices are moving into. As I say, obesity, prostate for example. These are all very much at the mature stage. Now it's a lot easier to outreach to a patient group in the mature stage because they have all the necessary resources and the focus with which to partner far more effectively than a group in the early stage here. So that is an important factor which you have to take into account. What is their capacity need to help you partner across their life cycle and across your lifecycle?

DO'S AND DON'TS OF PATIENT ENGAGEMENT

NH: I think the do's and don'ts can be summarized very, very simply in one single phrase, “building trust and relationships which in the long-term focus on common areas of high concern”. You're transparent with information which is both good and bad, and understanding what the patient group can do and what the patient group cannot do. If you're a large company, the patient group probably already know you and the product that you're working on for a small company.

And I would perhaps put some medical device companies here, you may not be on their radar screen where visibility is lower. Small companies cannot wait for patient groups to come to them. So ,in these instances you need to be comfortable in reaching out to the groups and pursuing a relationship with them. And the best way is not to fall into some of these common traps.

Do's and Don'ts Patient Engagement and Advocacy

- Do understand where the patient group is at in its stage of development
- Do identify areas of high common concern and unmet need
- Do understand the patients' needs and experiences
- Do clearly know what you want the patient group to do
- Do be in it for the long term
- Do align internally across the life cycle

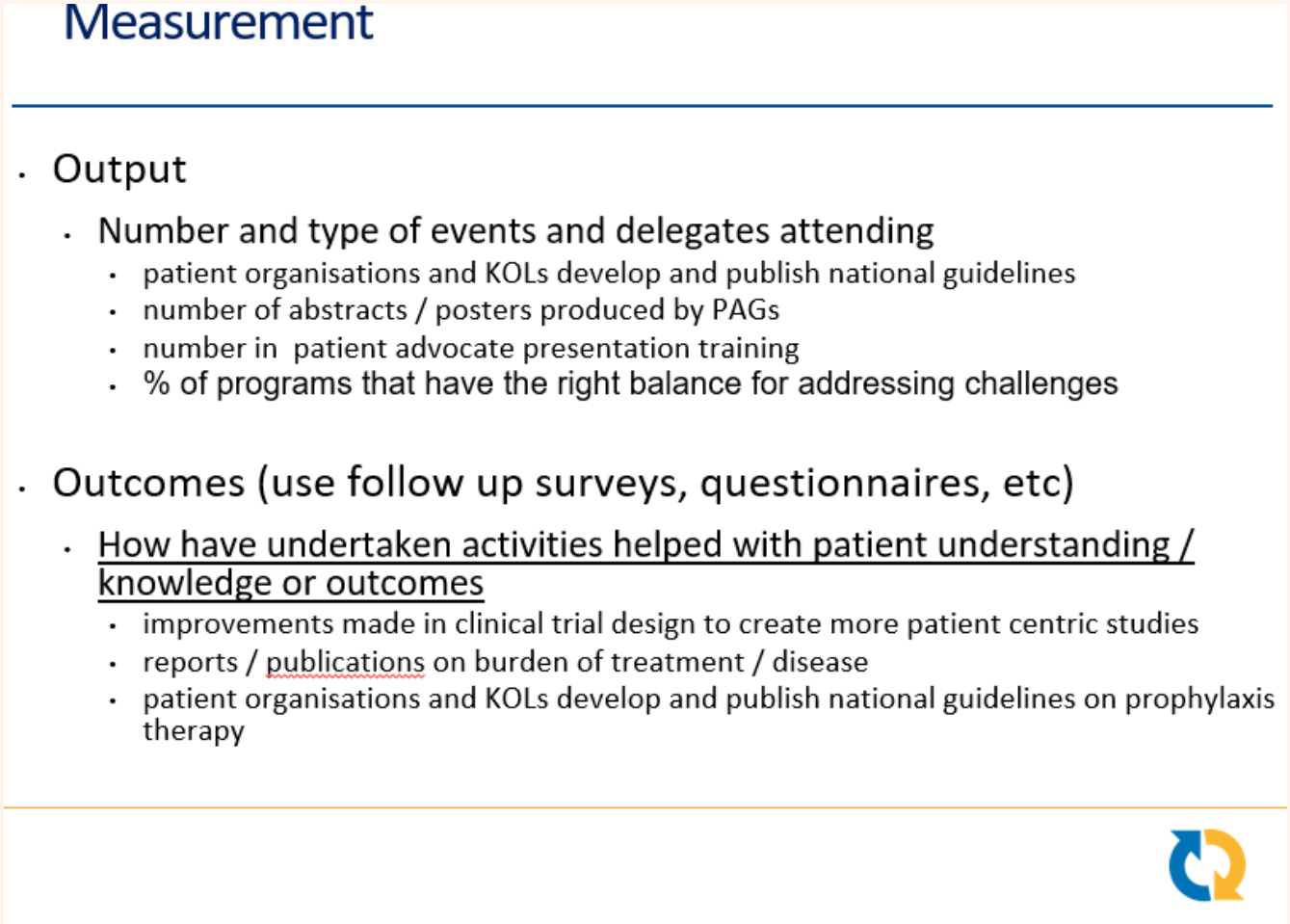
Do's and Don'ts Patient Engagement and Advocacy

- Don't go too fast in the early stages – build up trust and common aims
- Don't assume you will agree on all points – be ready for disagreement
- Don't bring in compliance late into the discussions
- Don't have complicated measurement metrics

MEASUREMENT

NH: Measurement is what I see as one of the big challenges for both pharma companies and any company wanting to participate in patient advocacy and engagement. I've deliberately kept this as busy to actually give you an idea of the in-depth measurement criteria which you need at both an output and an outcome stage.

And here it's important to make sure that you create the measurement which is relevant to the access challenge, which is what you're focusing on, which is relevant to the common shared challenge, which you're working on with the patient group and also one which is appropriate for the project.



FURTHER QUESTIONS?

Would you like a one-hour strategy session to discuss your specific challenge?

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