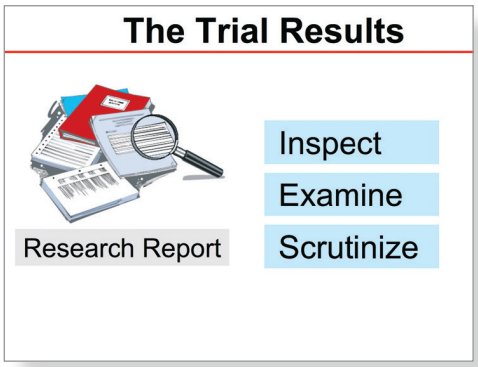
SECTION 3

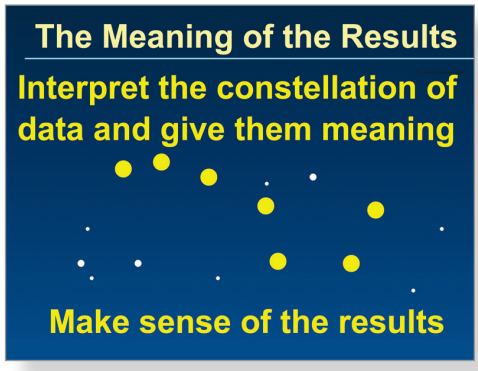
DEVELOPING YOUR CONTENT

Study the scientific results



A clinical trial yields a wealth of research results. There are usually primary and secondary parameters. Do your homework and inspect the scientific results thoroughly. Review them carefully. You may have to dig deeply. Enlist the support of colleagues from the clinical development or the medical marketing department, or of an outside consultant, to help you.

Interpret the data

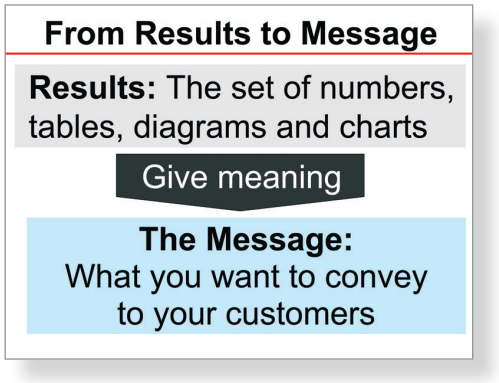


Give meaning to the results by answering the following questions:

- what does the data mean to the doctor?
- how do you interpret the results so that they are relevant to the doctor?
- which conclusions can you draw for the practice of medicine?

This task takes a razor-sharp mind, time and commitment. Do *not* expect your advertising agency to do this for you – they usually lack both the medical expertise and the research background.

Develop your message

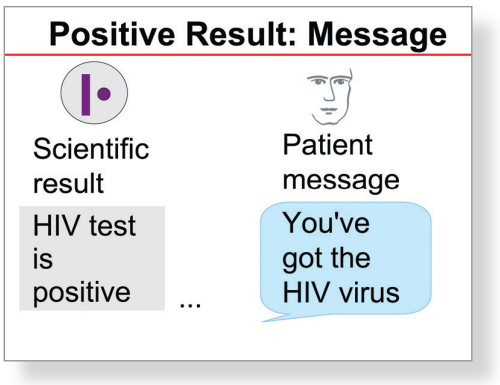


Based on the trial results and the meaning you attribute to the scientific findings, develop answers for the following questions:

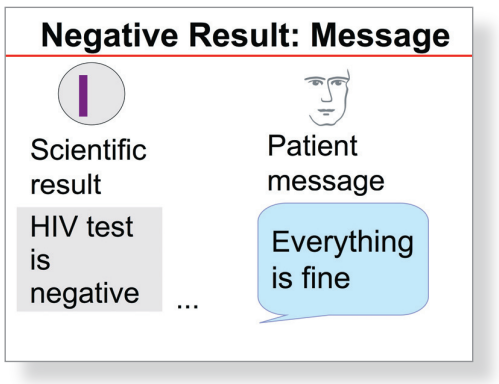
- what is your core message?
- what do you want to communicate?
- what is your story?

Take the time to think.

Ensure that your message is based on scientific evidence.

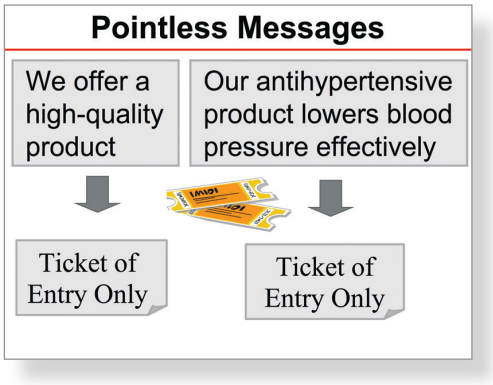


An HIV (human immunodeficiency virus) test usually shows either a positive or a negative test result. A *positive* test result is bad news for the patient (who has been infected with a deadly virus). A positive result implies the following message to the patient: 'You are infected with HIV'.



A *negative* HIV test result usually means that the patient has not developed antibodies against the human immunodeficiency virus: positive and encouraging news for the patient. The underlying message is: 'Everything is fine'. However, a poorly developed and communicated message can have devastating consequences. In the past, patients told that 'Your HIV test is negative' have misinterpreted the statement as meaning 'You have the disease'.

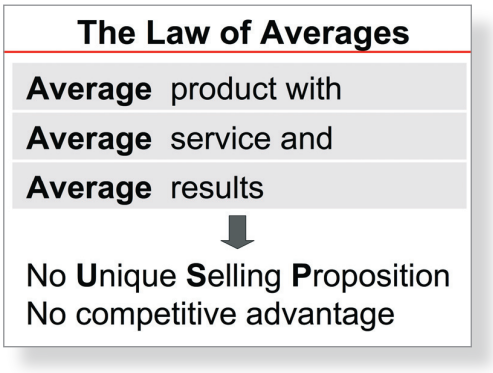
Avoid irrelevant messages



One company for which I undertook consultancy work considered promoting their new product as a 'high-quality' product. However, most products on the market were considered 'high-quality' products. Hence this is a marketing approach that does not communicate any competitive advantage. We therefore changed the message.

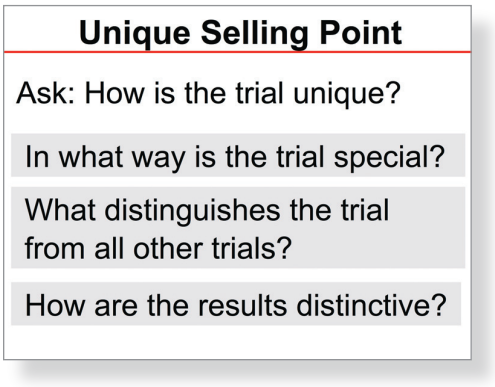
A second company marketed their new blood-pressure-lowering drug as 'effectively reducing blood pressure'. Yet this is exactly what you would expect of all blood-pressure-lowering drugs. Once again, this approach does not communicate any competitive advantage.

Look for competitive advantages



The market is flooded with competing products using similar messages. Are the characteristics of your product, your service and your trial results different from those of your competitors? Does your message convey a competitive advantage?

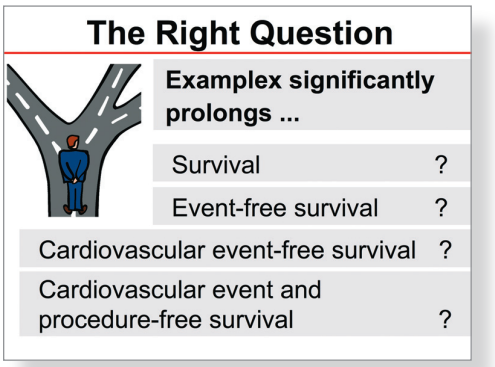
Work the angles considering all data



Look for an angle that lends support to a unique or special claim for your drug. You need to stand out from the crowd. This is not about being experimental or extravagant in your claims, just about being distinct. Ask yourself: how is your trial special or unique in design or results? How are the results relevant to better patient care?

Always communicate a balanced risk-benefit ratio.

Ask the right questions

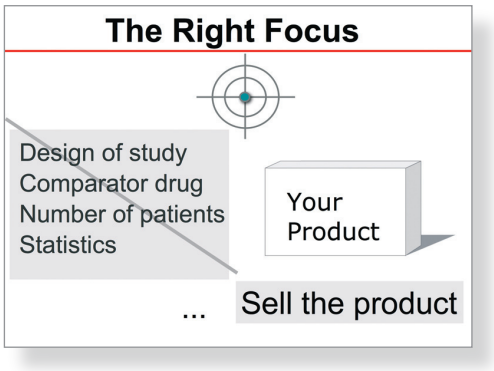


There are often nuggets of information you can extract from the wealth of research results. Information needs to be both clinically relevant and helpful in distinguishing your product by supporting a competitive advantage. Sometimes asking yourself the right questions can help identify the appropriate answer in the research data. Probe in different directions. The example shows how you can fine-tune your questions.

Seek insights from the investigators

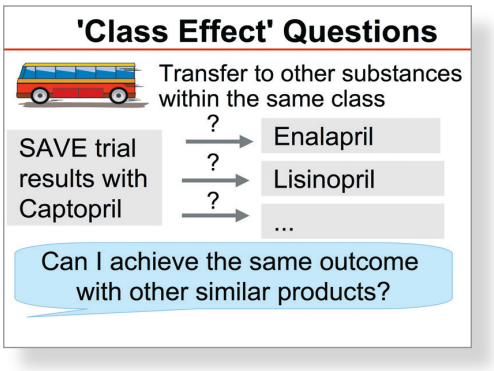
The clinical researchers who undertook the trial form a huge knowledge base. Talk to them. Ask your medical colleague to introduce you. You will usually be given a warm welcome. Make time for a chat with them. What were their experiences of the trial? What impressions and ideas can they offer?

Set the right focus



You need to emphasize the benefits of the product and not the characteristics of the trial. Details about the number of patients, design of the trial, statistical considerations, comparator drugs and so on should be kept firmly in the background. Highlight what the product can do for the doctor and the patient. Always remember: 'Sell the product, not the trial'.

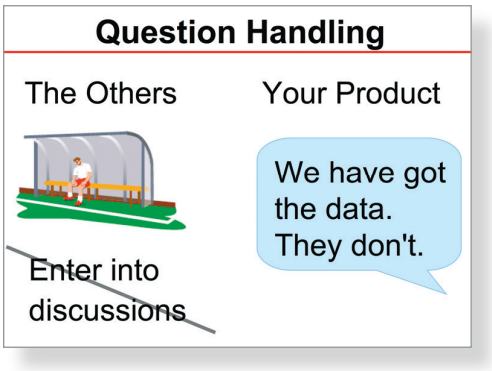
Beware of questions about the 'Class Effect'



The 'class effect' refers to the potential interchangeability of substances within the same chemical class. Experts like to raise this sensitive issue during symposia and workshops: 'Can the study results be transferred to other substances within the same class?' or 'Can I achieve the same outcome with other similar products?'

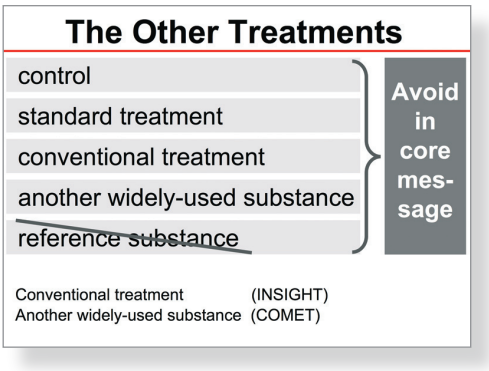
One example involved a discussion about the clinical equivalence of ACE inhibitors (a class of antihypertensive drugs). The SAVE (Survival and Ventricular Enlargement) trial done with the ACE inhibitor Captopril showed results in favour of that substance. Captopril reduced the risk of mortality attributed to cardiovascular events by 21 percent.

Keep tight-lipped about theories



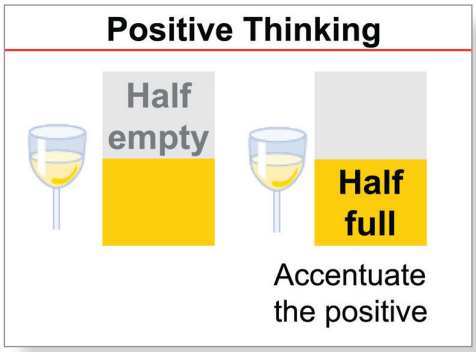
The company sponsoring the SAVE trial and subsequently marketing Captopril was Bristol-Myers-Squibb. When a representative was asked the 'class effect' question, his answer was along the following lines: 'We have the data, they don't' (with 'they' implying the competitors). Use similar statements if you are asked similar questions and leave it at that. This is one of the rare occasions when you should be absolutely tight-lipped. Resist the temptation to speculate. You have the scientific evidence and the other companies do not.

Learn the power of language



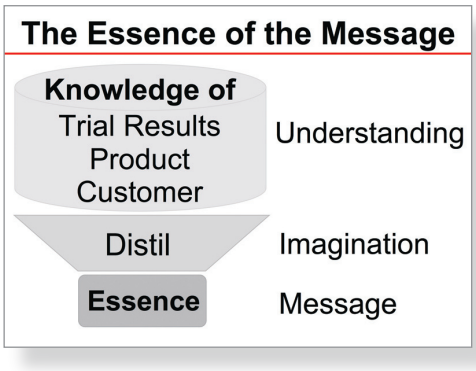
In your discussions, you may need to talk about alternative forms of therapy. How should you refer to them? When discussing the INSIGHT trial, Bayer used the term 'conventional treatment' or 'standard treatment' to describe the diuretic treatment arm. When justified by the results, these terms establish the expectation of a treatment improvement. In the COMET, Carvedilol or Metoprolol European Trial, metoprolol was referred to as 'another widely used substance', essentially a neutral description. You should avoid the term 'reference substance' because this implies the definitive treatment. Your final message should always highlight your product and not the other form of treatment.

Think positive



Successful marketers have a mindset that focuses on the positive. This is a useful approach for marketing clinical trials. Marketers don't consider the glass half empty; for them it is half full. They don't ignore negative aspects, but they are able to highlight the positive and desirable ones. Keeping the right balance between the two and appropriately representing the risk-benefit-ratio of a drug is an art that can be learned.

Capture the spirit



You need to distil your detailed knowledge:

- of the trial results
- of the product characteristics, and
- of the customers' needs

into its essence. This task requires understanding and imagination. A clear and original message is crucial if you are going to communicate your competitive advantage successfully to your customers.

Create a convincing message

A Convincing Message

Concise	Short and to the point
Clear	Easily understandable
Credible	Endorsed by reliable sources
Consistent	Repeated in a uniform way

What makes a message convincing and compelling?

- Make it concise = short and to the point
- Make it clear = easily understandable
- Make it credible = in line with other information and endorsed by a reliable source
- Make it consistent = repeat the same message to all the people you communicate with (uniformity across people and time).

Keep it simple

A Clear Message

Keep things brief and clear

~~Everything is important~~

Keep **i**t **s**hort and **s**imple

I know that details matter. As a medical director, I was responsible for ensuring that every detail of an advertisement adhered to regulatory requirements. However as marketer, I have learned to keep things short and simple: brief is better than long. You need to boil down and condense complex issues into clear, concise and crisp claims that everybody can understand. Keep the details for the specialists. There is no need to say everything. If in doubt, compress, reduce, shorten, abridge and summarize.

Major Results of XYZ Trial

The clinical study of A versus B resulted in risk reductions of

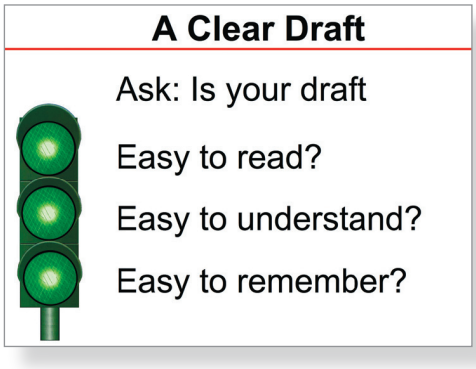
Primary endpoint
- 8% in all-cause mortality (non-significant trend: p=0.128)

Secondary endpoints
- 12% in combined all-cause mortality and all-cause hospitalization (p=0.002)
- 10% in cardiovascular mortality (non-significant trend: p=0.073)
- 8% in combined all-cause mortality and cardiovascular hospitalization (p=0.036)
- 9% in combined cardiovascular mortality and hospitalization (p=0.027)
- 8% in fatal and non-fatal … and hospitalization … (p=0.374)

Post-hoc analysis
- 15% in combined all-cause mortality and hospitalisation … (p<0.001)

This piece is based on a real example. The original trial name has been changed to 'XYZ Trial'. The readers cannot see the message when confronted with all this complex information, nor will they bother.

Check for clarity

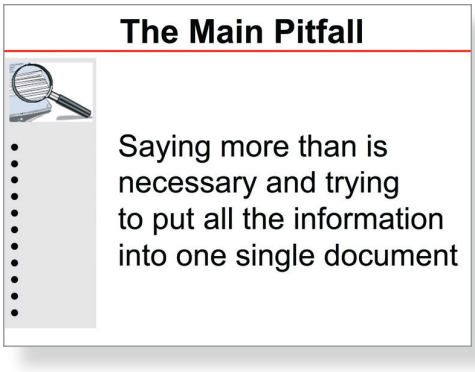


Once you have developed a draft, please check:

- is it easy to read?
- is it easy to understand?
- is it easy to remember?

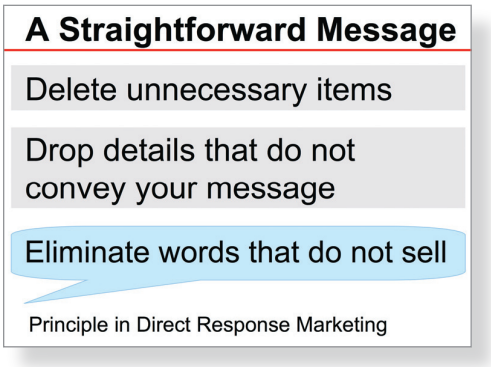
If you do not get a green light on all three items, change and simplify your draft.

Avoid pitfalls when developing content



The most common mistake is to put too much information into one piece or document — whether it is an advertisement in a journal, a detail-aid folder for the sales force or a brochure for physicians. It is tempting for someone with a strong orientation toward research to try and cram too much information into a single document. These overloaded documents drown your message and your prospect will not even bother to read them.

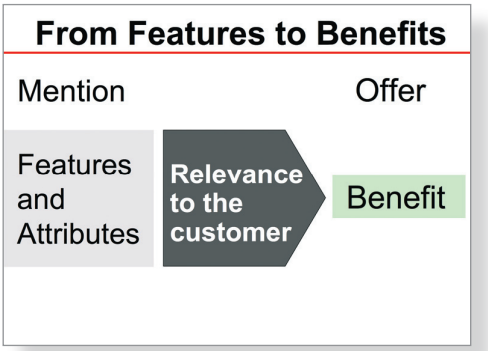
Be concise



Keep everything you do straightforward. Avoid superfluous words, styles, symbols and images. Pull out all the stops in your language while making sure that you represent the right risk–benefit ratio of your drug. Do not communicate more than is necessary: too many cooks spoil the broth and too many details confuse your message. Eliminate any details that do not help you convey your message:

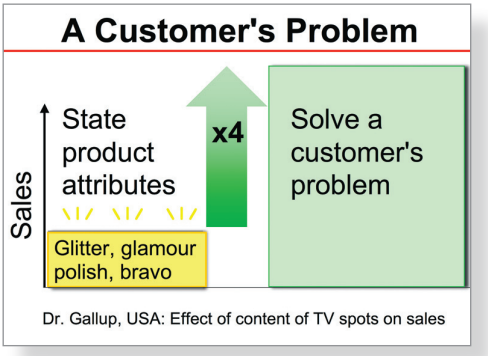
- use simple language
- cut any words that do not sell
- satisfy the need for a quick read.

Move from Features to Benefits



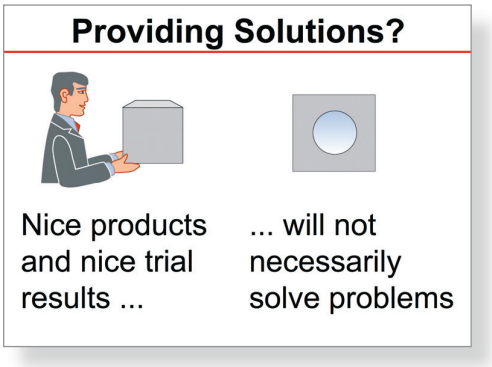
The customers are not interested in those features of your product or trial that have no relevance to their life (for example, details of statistical analysis). They are only interested in the potential benefits that you and your company can provide. Leaving human appreciation and financial rewards aside, your main benefit consists in solving a health problem.

Solve customers' problems



Dr Gallup investigated the effect of the content of televised commercials in the US on subsequent sales for certain consumer goods. He found that – compared to stating product attributes ('the glitter and the glamour') – commercials that purported to solve a customer's problem resulted in sales that were four times higher. The conclusion: solve a problem and increase revenue.

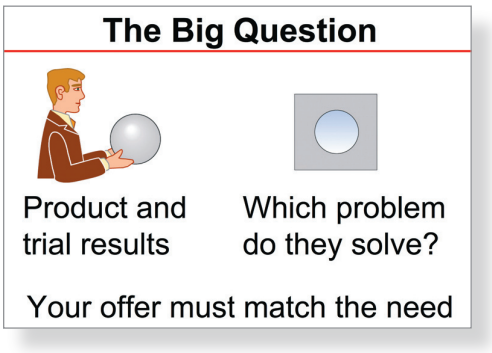
Offer solutions



Why should your customers care? Are you helping them solve a problem? Are you helping them to find an answer to a question in their professional lives? Do you meet an unmet need? Is there a fit between what your customer needs and what you offer?

A new pharmacological breakthrough or the amount of substance used per tablet do not qualify as elements of a solution. Case in point: one pharmaceutical company built their message around the small dosage the patients had needed to take. They had prominently displayed the term 'microdose' in their advertisement campaigns for a cardiovascular drug. They realized later that this feature does not lend itself to a convincing argument for the prescribing physician. They ultimately changed the slogan.

Follow the solution imperative



The following questions sound straightforward, but are essential to your success:

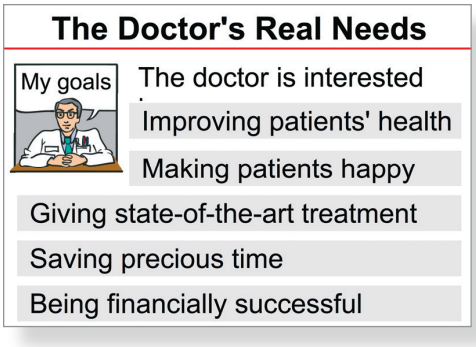
- which specific problems do you solve with your product and your trial results?
- are you sure that it is a problem or an unmet need for the doctor?

If your customers are not aware of a problem, they will not listen to you.

Work on these questions, until you have found a satisfactory answer.

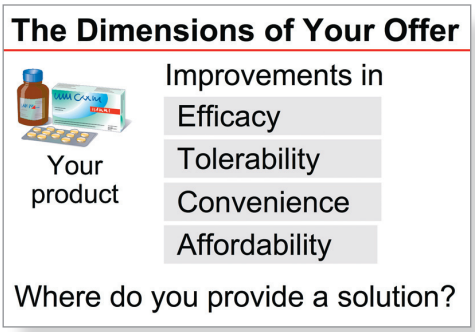
You may need to sharpen doctors' awareness for particular problems. For example, companies marketing lipid-lowering drugs (especially statins) have successfully increased physicians' awareness of the risks of hyperlipidemia and the healthcare benefits of treating this condition resulting in tremendous product revenues.

Understand the real needs



Focus on the key areas in which doctors seek better solutions. Ensure that you provide the doctors you are targeting with solutions to the problems that concern them. Give them only the support they are really interested in.

Pin down your solution

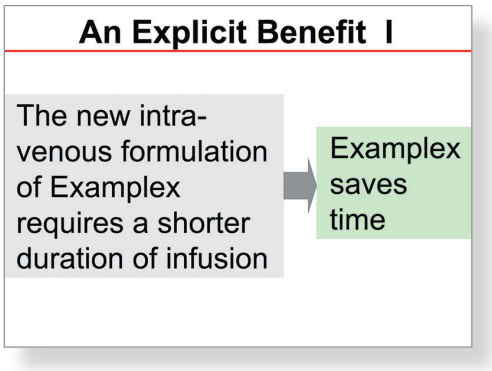


For most diseases, there are four areas in which your product can provide a solution. It may offer improved:

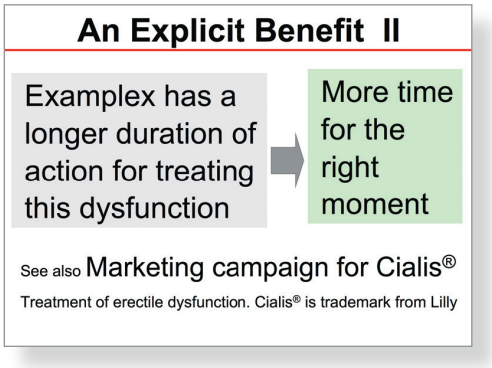
- efficacy (desired pharmacological effect)
- tolerability (the profile of side effects)
- convenience (user-friendliness)
- affordability (price).

You need to identify which of these elements is true of your drug.

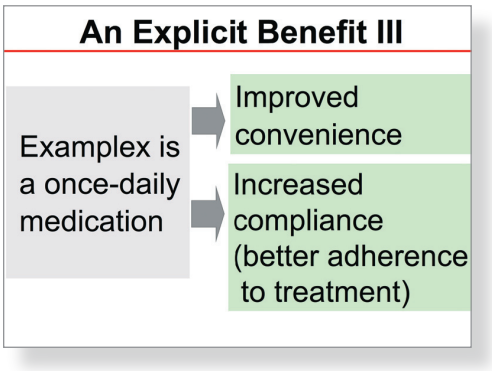
Communicate explicit benefits



The illustration shows how a shorter duration of infusion for a new drug results in a clear advantage for the patient and the healthcare professional. He or she saves precious time. This may seem obvious to you, but spell it out. Do not leave it to the physician to work out how features translate into benefits. Specify the benefit clearly.

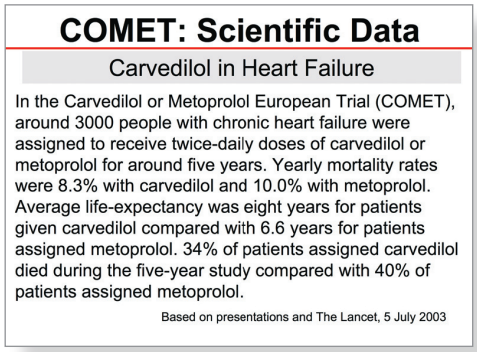


This example shows how the pharmacokinetic feature of a longer duration of action and a longer half-life translate into a clear benefit. The concept ‘more time for the right moment’ is successfully used by the company Lilly for their product Cialis® in the treatment of erectile dysfunction.

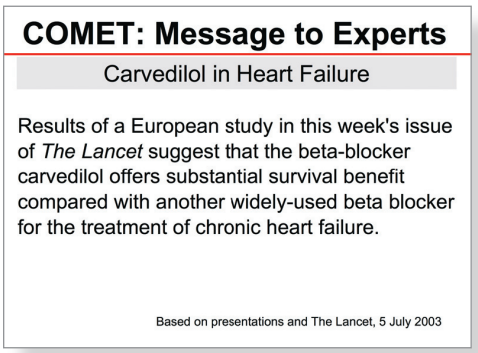


The once-daily administration of a medication results in better convenience and adherence to treatment (patient compliance) compared to a twice-daily medication.

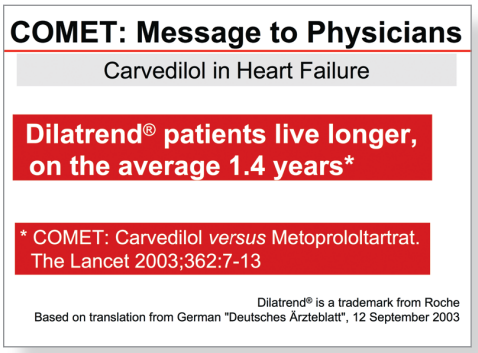
Practical examples – The COMET Case Study



The **C**arvedilol **o**r **M**etoprolol **E**uropean **T**rial (COMET) included around 3000 people with chronic heart failure.

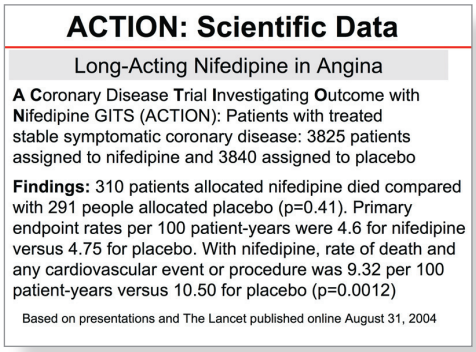


Based on these results, the company conveys a clear message targeted at experts and opinion leaders.

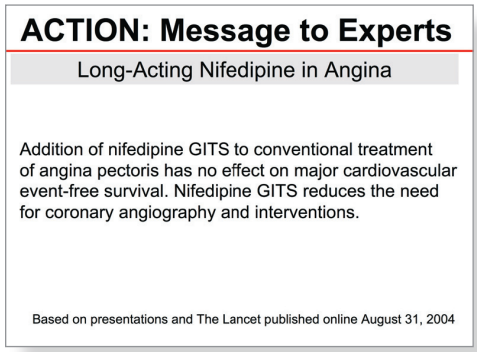


A clear message targeted at prescribing physicians.

The ACTION Case Study



A **C**oronary Disease **T**rial **I**nvestigating **O**utcome with **N**ifedipine GITS (ACTION) investigated the effect of long-acting nifedipine in patients with coronary artery disease.



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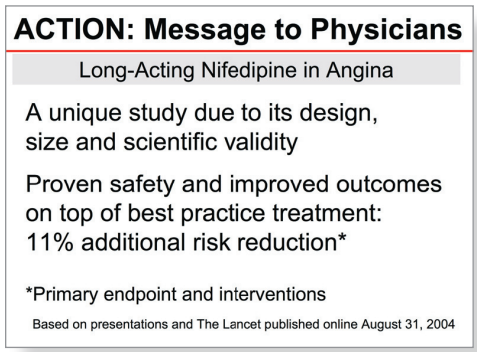
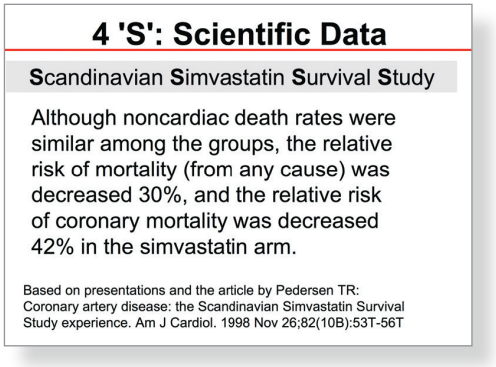
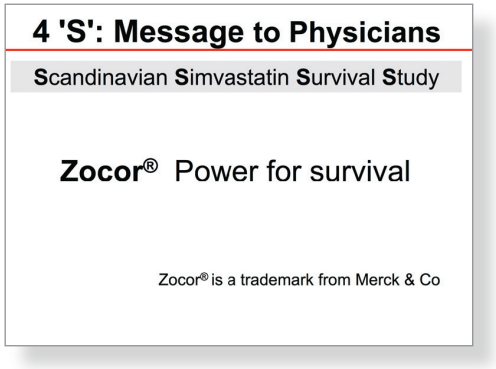


A clear message targeted at prescribing physicians

The 4'S' Case Study

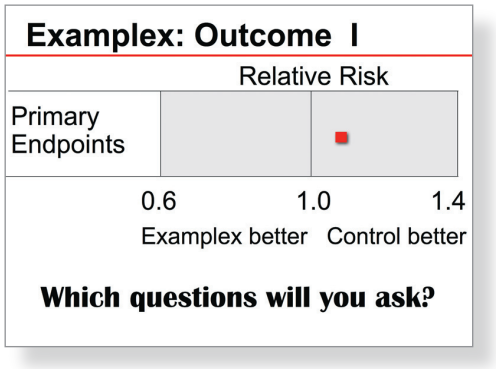


The **S**candinavian **S**imvastatin **S**urvival **S**tudy investigated the effect of simvastatin in patients with hyperlipidemia.



Based on these results, the company conveys a clear message targeted at prescribing physicians.

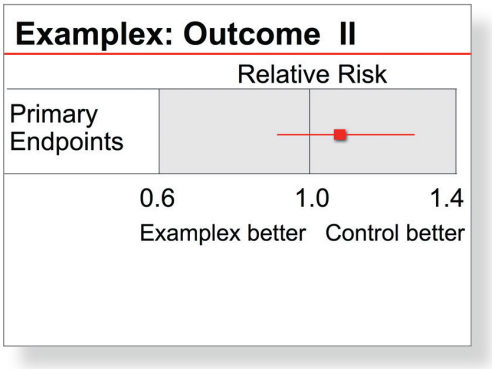
The Examplex case study



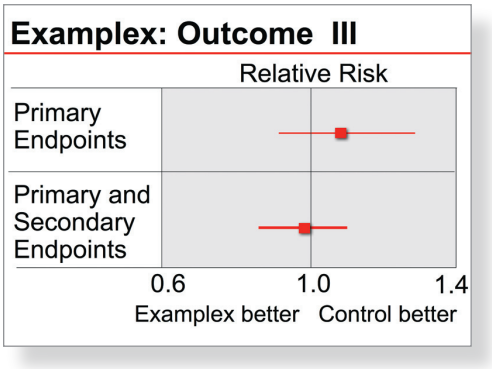
Our example company spent millions on a large international high-quality trial involving several thousand patients with a cardiovascular disease. We will call it the Examplex trial. The data were analysed.

You are the product manager responsible for product 'Examplex'. What set of questions will you ask? Subsequent illustrations show you how to use these questions to move through various drafts and arrive at a final version that provides a far more balanced view of the study results.

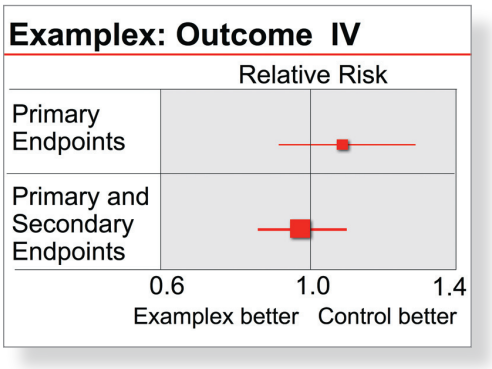
The Examplex case study (cont)



The answer to a question for your statistician or medical advisor: 'What are the statistical confidence intervals for these endpoints?' will result in this diagram.

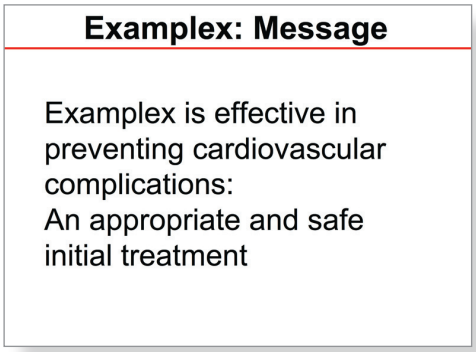


Asking your statistician or medical advisor 'What are the results for primary and secondary endpoints in this study?' results in this variation to the diagram.



Asking your statistician or medical advisor 'How many of the individual data sets contribute to the primary and to the secondary endpoint?' results in this diagram. The diagram has now shifted in favour of your product, although you cannot construe a clinically relevant difference between the two treatment arms. Is this a fair representation? Yes it is, because the combined number of primary and secondary endpoints is usually more relevant to practising physicians who see the patients in their medical practice – independently of whether an endpoint met the required strict adherence to study protocol criteria which would qualify it as primary.

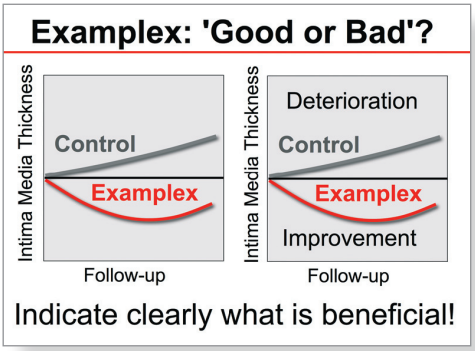
The Examplex case study (cont)



The substance used as active control in this trial was standard treatment in the disease investigated. Prior clinical studies had clearly demonstrated it prevented cardiovascular complications. Since this trial found no relevant difference in efficacy between the active control and the substance Examplex, Examplex can be considered as having similar beneficial effects to the active control. This leads to the message expressed in the example.

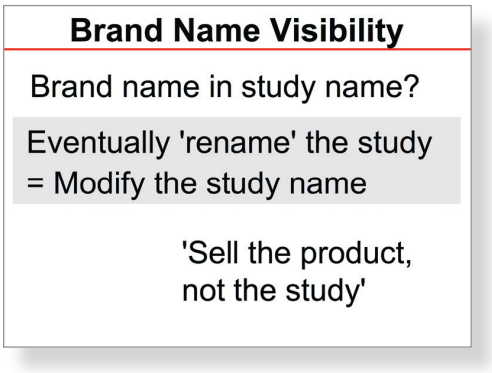
Be sure to discuss this with your medical department and check regulatory requirements in your country before promoting any message.

If the efficacies of your product and the active control are similar in your trial, check the profile of side effects. Examplex has a better tolerability profile than the comparator.



In some charts the increases or decreases of sonographic, radiological and laboratory parameters are not immediately apparent to the reader as a benefit or a disadvantage. You need to indicate clearly what is beneficial! The illustration shows one way to illustrate that the decrease in 'intima media thickness' associated with Examplex is indeed a desirable outcome. Place the word 'improvement' on the appropriate side of the horizontal axis so that the reader instantly recognizes this change as a favourable result.

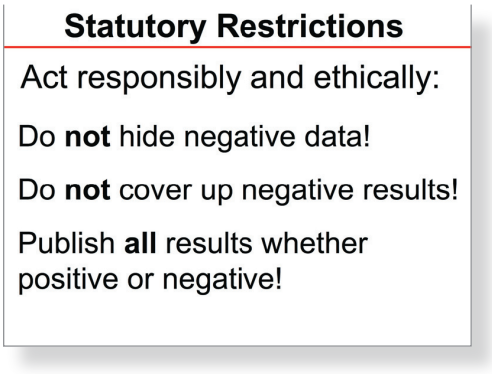
Sell the product not the study



Is your product mentioned in the name of the trial? What do you do if your brand name is not part of the study name? You could 'rename' the study internally so it reflects your brand name. In most cases, it is enough simply to put the product name before the study name (usually an acronym) when you refer to it. For example, the name of your product is 'Examplex' and the acronym of the study is 'ABC'. Your clinical trial name becomes the 'Examplex ABC study'. Make sure your team agrees to use the new term consistently in all your internal and external material to ensure the biggest impact on prescribing behaviour.

A trial where the impact on sales of the substance investigated was very limited, was the HOT (Hypertension Optimal Treatment) trial – well known in the cardiovascular sector. However, only few prescribing physicians knew which was the main drug used in the trial (it was the calcium antagonist felodipine).

Know and respect statutory limits

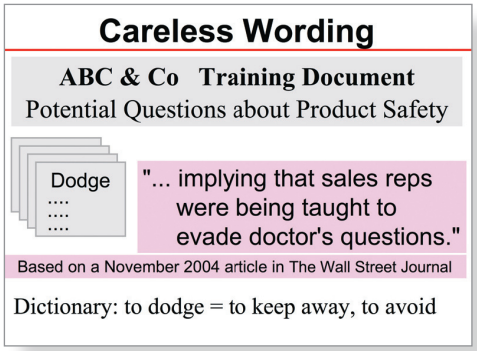


You should ensure compliance with all relevant standards. See chapter entitled 'Codes of Practice'. Your reputation and your credibility are your most valuable assets amongst your direct customers, the public and governmental agencies. Various incidents in late 2004 and early 2005 prompted government agencies to enact regulations that will require pharmaceutical companies to publish the trial results of all completed clinical trials that they have initiated. Companies that conceal trial results (for example, because they do not favour their product) are providing a disservice to their customers and their product.

Handle 'negative data' appropriately

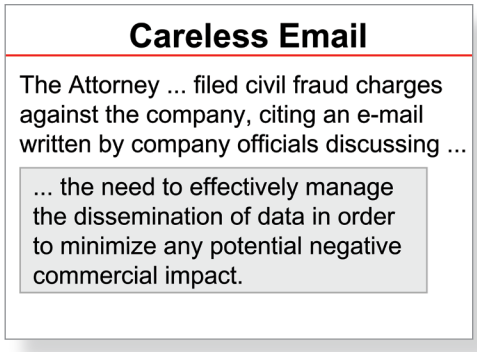
One example for handling data from clinical trials is illustrated on the website www.lillytrials.com, where the company Eli Lilly will publish all of its clinical trial results. Visit this website to see how they do it.

Choose your words with care



An article published in *The Wall Street Journal* commented on the use of the word 'dodge' in a company's training document that instructed sales representatives on how to deal with potential questions about the safety of their product. The training document could be interpreted as '... implying that sales representatives were being taught to evade doctors' questions.' The importance of responsible behaviour is obvious. In addition, be careful in your choice of words when writing your training manuals. Therefore watch what you write!

Beware careless emails



The Washington Post carried an article (26 August 2004) describing how the New York Attorney General Eliot L. Spitzer filed civil fraud charges against a big pharmaceutical company while citing an email in which company officials discussed certain studies and the need to manage effectively the dissemination of data in order to minimize any potential negative commercial impact. This incident shows how careless behaviour and careless emails can be loose cannonballs which can lead to legal proceedings against you and your company.