SKIM | Biosimilars

How to stay competitive against a new wave of entrants?

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Topics for today

1. Biosimilar introductions
2. Success of biosimilars
3. Factors protecting from biosimilar uptake
4. Influencers on biosimilar uptake
5. A case study in the area of rheumatology

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What are the differences between biologics and biosimilars?

? **What are biologics?**

? **What are biosimilars?**

≠ **Biosimilars are not generics**

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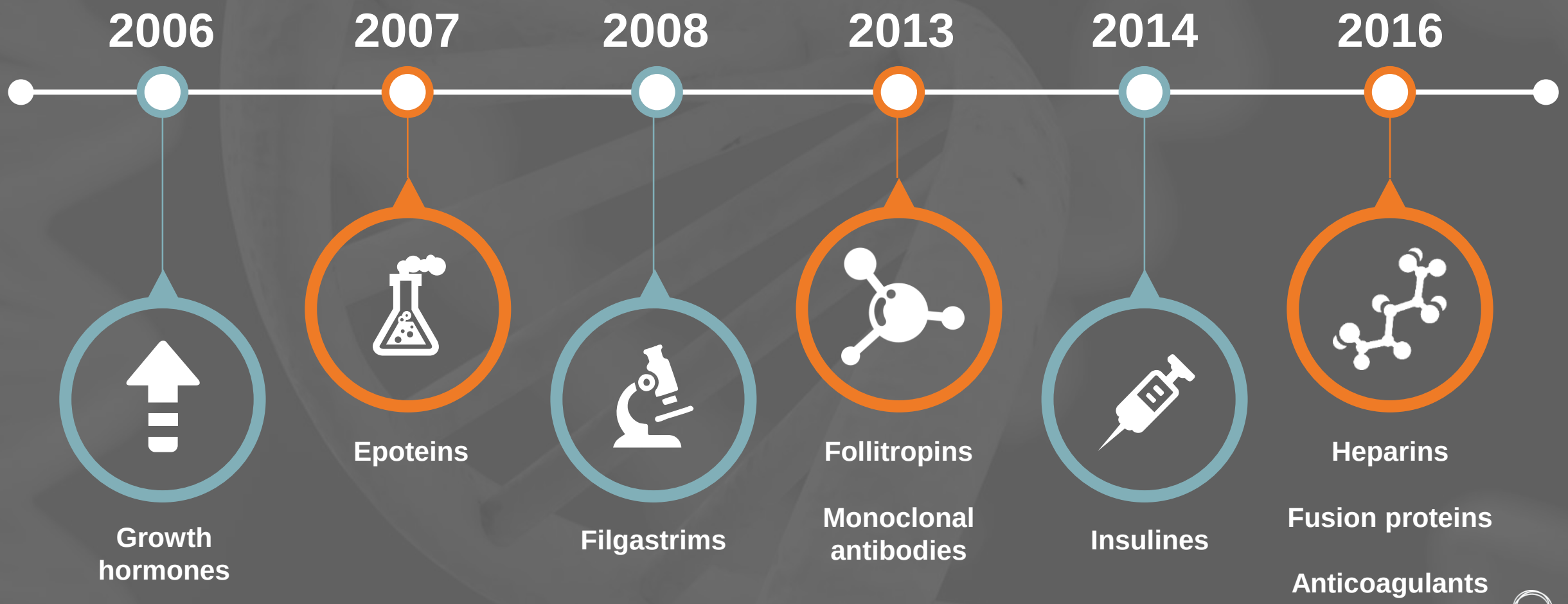
Biosimilar introductions



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Why are biosimilars successful?

$154bn

Global spending on biologics

$110bn

Global savings by using biosimilars

30%

Price discounts averaging around

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How to protect for biosimilar uptake?

Price

Brand power

Value added services

Innovation

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Who and what influences biosimilar uptake?

Competitive Landscape

Who?

What?

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Who?

Payers

National health organizations

Key Opinion Leaders

Physicians

Patients

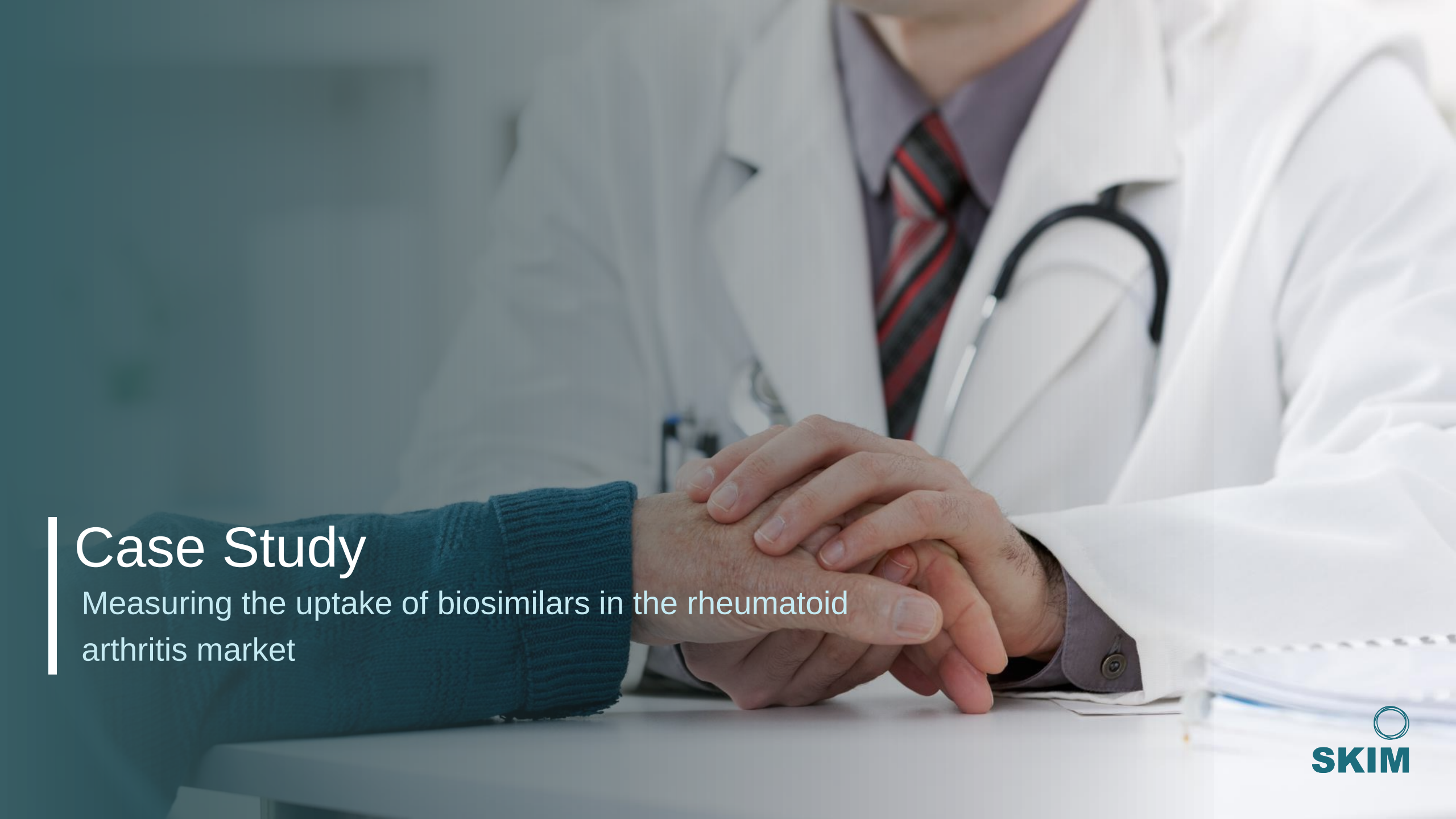
What?

National / regional guidelines or recommendations

Gain share agreements

Prescribing quotas

Evidence generation



Case Study

Measuring the uptake of biosimilars in the rheumatoid arthritis market

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How to measure biosimilar impact?

Fixed part

Biosimilar product profile

Efficacy	Comparable to originator product
Safety	Co
QoL	Co
Dose regimen	Co
Mode of Action	Co
Expected indication	Co

Variable part

Biosimilar product profile

Price relative to originator product	10% cheaper	20% cheaper	30% cheaper	40% cheaper	50% cheaper	60% cheaper
Endorsement from health authorities	Use originator brand in any patients according to license	Use originator brand in any patient according to license – but reimbursement will ONLY at lowest price	Proactively identify patients stable on branded product who could be switched to the biosimilar	Use biosimilar only in new initiated patients	Use biosimilar in all patients	No endorsement in place
Clinical data	Phase I study to demonstrate equivalent pharmacokinetics and safety versus originator product Phase III study to demonstrate equivalent efficacy and safety compared with originator product in 1st line treatment only	Phase I study to demonstrate equivalent pharmacokinetics and safety versus originator product Phase III study to demonstrate equivalent efficacy and safety compared with originator product in 2nd line treatment only	Phase I study to demonstrate equivalent pharmacokinetics and safety versus originator product Phase III study to demonstrate equivalent efficacy and safety compared with originator product in 1st and 2nd line treatment			
Value added service	Home care services	Patient and HCP support program	No value added services			

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Patient allocation with physicians

Measuring the uptake of biosimilars in the rheumatoid arthritis market in three steps:

STEP 1	STEP 2	STEP 3
Measure the current market (including the existing biosimilars on the market for infliximab and etanercept)	**Measure the impact of future new products (including new biologics and the new biosimilar)**	**Measure the impact of the different product characteristics and price levels**

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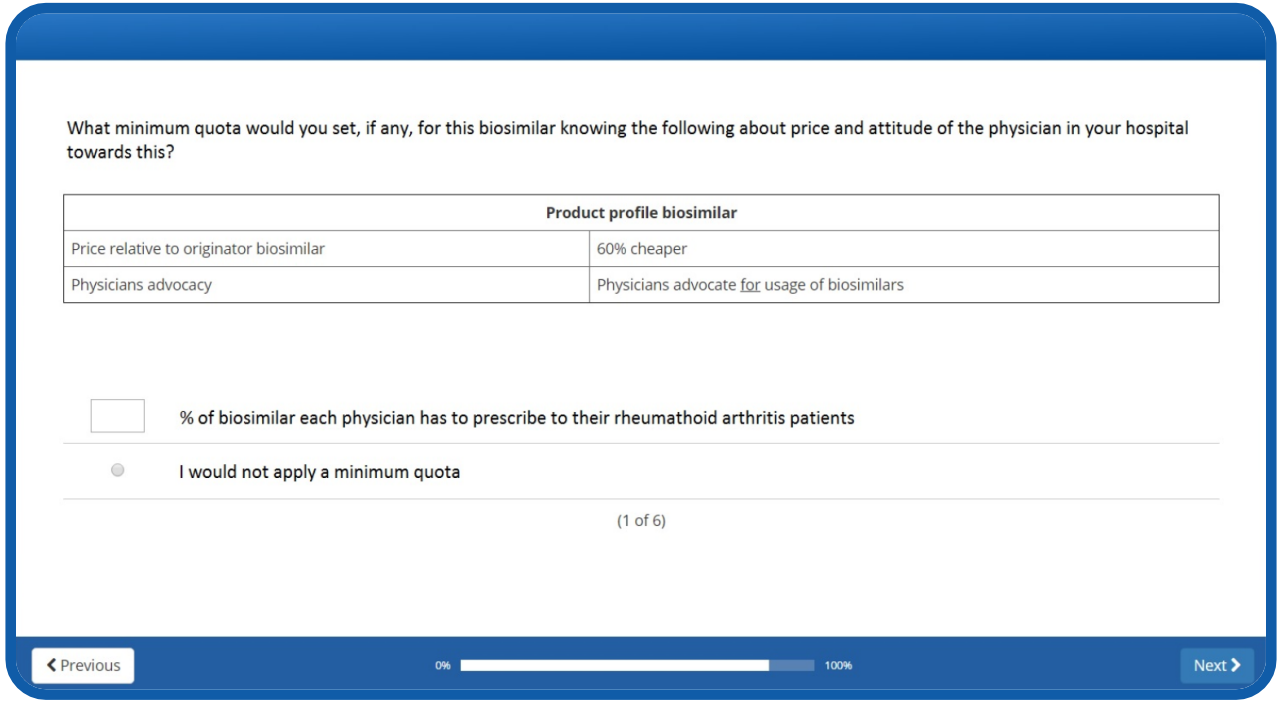
How to measure stakeholder influence?

High influence of hospital pharmacist on physicians treatment decision

Choice exercise to set quota on proportion of patients receiving new biosimilar

Quota outcomes per price point tested for physician model



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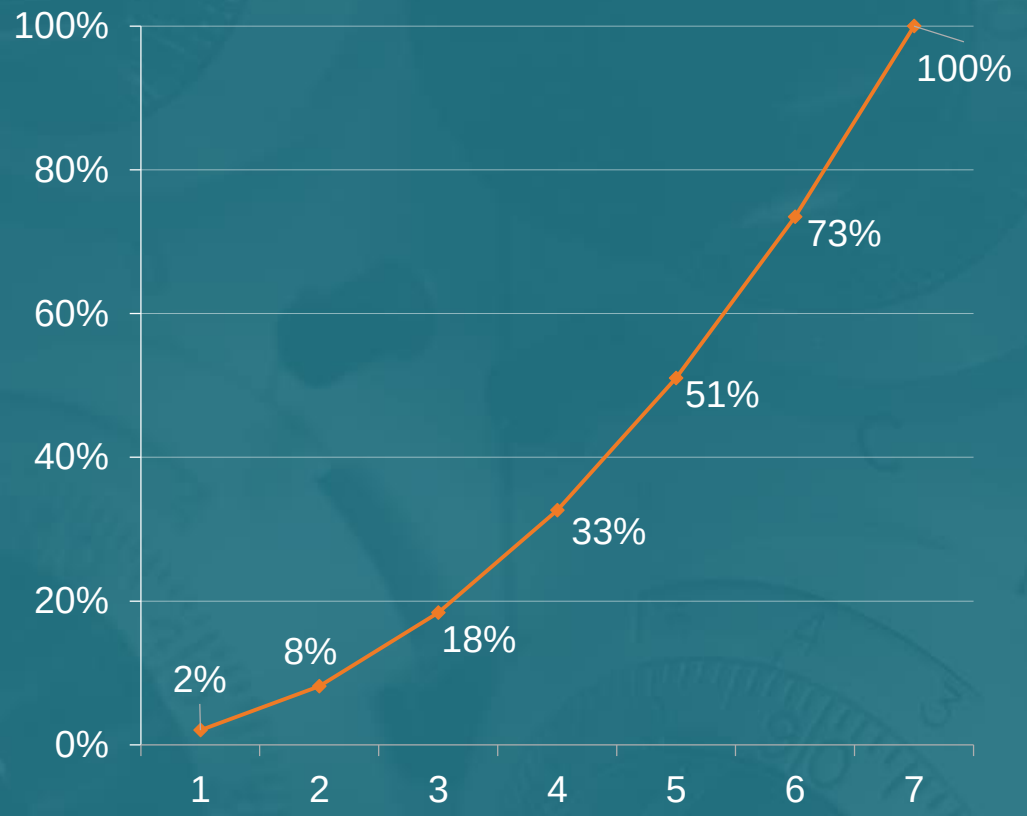
Applying weights

Physicians often overestimate the proportion of patients they would prescribe to that new product.

We will use the respondent's answer to a 7-point "likelihood to Rx" Likert scale for each the new biosimilar to calibrate for overstatement

Reduction Factor
(to be multiplied by patient share)



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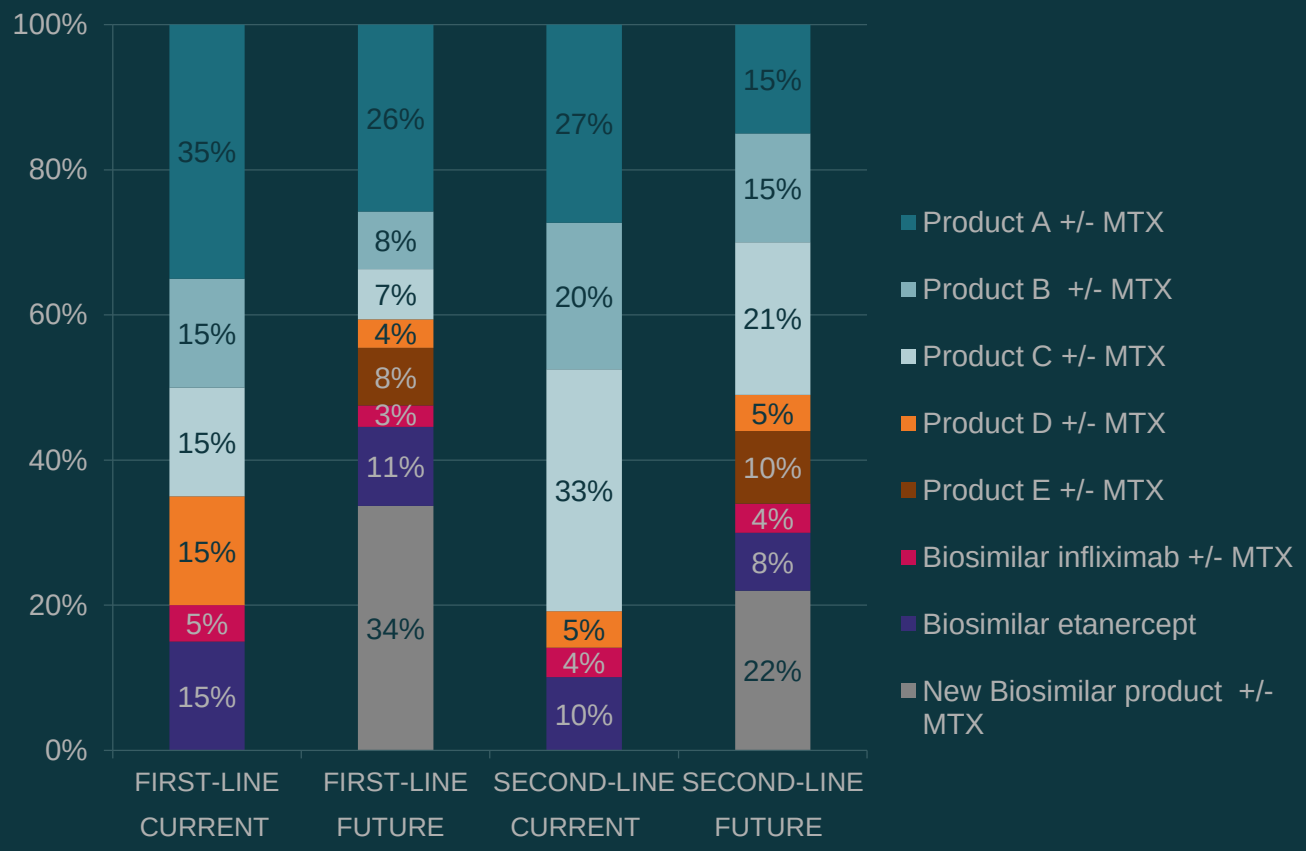
Outcomes of forecast data



Scenario modeled

- Biosimilar price: 30% cheaper compared to originator product
- Endorsement: use biosimilars in all patients
- Phase I study to demonstrate equivalent pharmacokinetics and safety versus originator product, Phase III study to demonstrate equivalent efficacy and safety compared with originator product in 1st and 2nd line treatment
- No value added services in place

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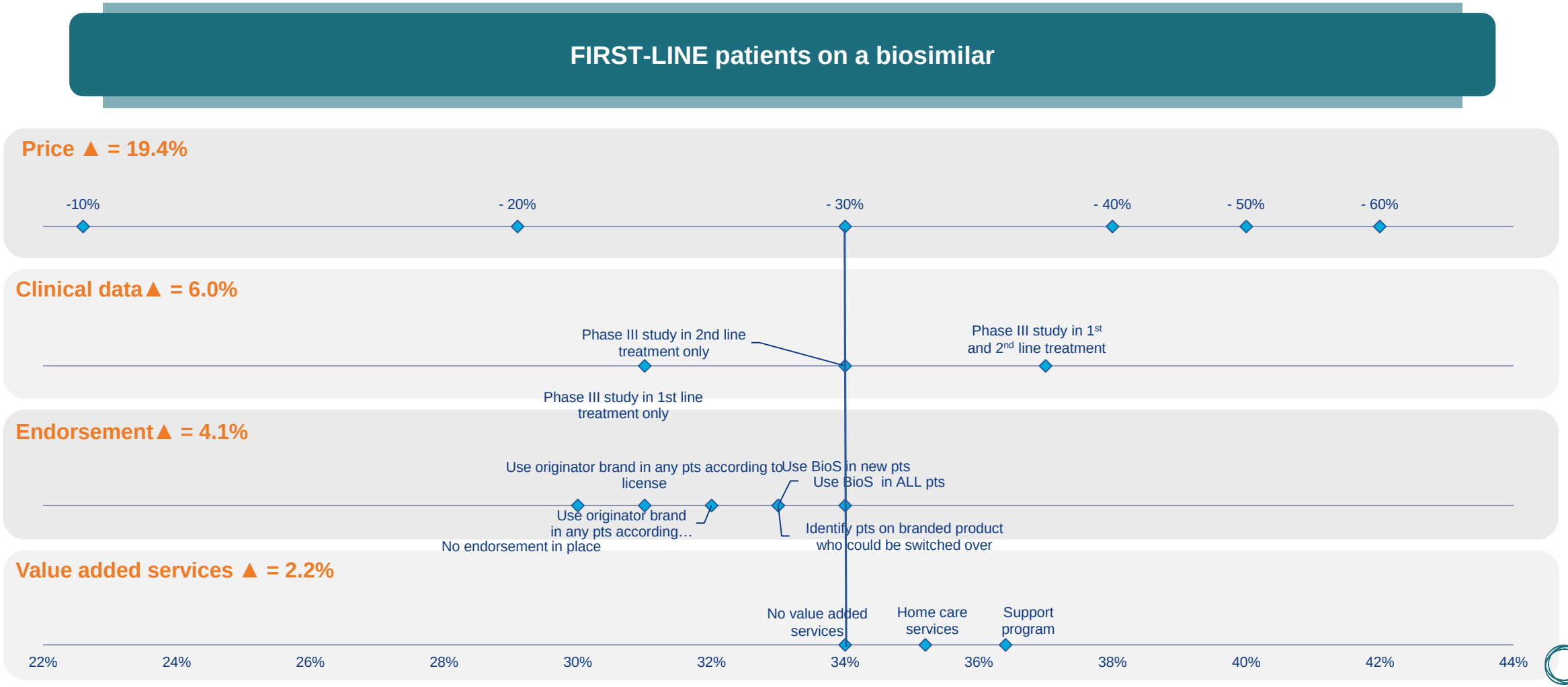
Outcomes of importance data



Market simulator as key deliverable

press here to restore a particular scenario

Biosimilar

Price relative to originator product	40% cheaper
Endorsement from health authorities	Use biosimilar in all patients
Clinical data	Phase I study to demonstrate equivalent pharmacokinetics and safety versus originator drug Phase III study to demonstrate equivalent efficacy and safety compared with originator drug in 1st line treatment
Value added servics	No value added services in place

Physicians advocate **for** or **against** usage of biosimilars: **for**

% of biosimilar each physician has to prescribe to their RA patients: 38.0%

calibration: TRUE

weights: TRUE

figures: preference share under currently defined scenario & (▲ from current)	FIRST-LINE biologic	SECOND-LINE biologic + later
Product A +/- MTX	26% (▲-9%)	15% (▲-12%)
Product B +/- MTX	8% (▲-7%)	15% (▲-5%)
Product C +/- MTX	7% (▲-8%)	21% (▲-12%)
Product D +/- MTX	4% (▲-11%)	5%
Product E +/- MTX	8%	10%
Biosimilar infliximab	3% (▲-2%)	4%
Biosimilar etanercept	11% (▲-4%)	8% (▲-2%)
New Biosimilar	33%	22%

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Key take-aways

Price is the main driver of biosimilar prescription, but not the only driver

Know who your competitors are and will be in the future

Know who and what influences biosimilar prescription

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decision behavior experts

Thank you

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