



RUTGERS

iJOBS Workshop: Life Science Consulting

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Objectives

1. Talk about what a “Consultant” does on a daily basis
2. Work as a team in a project simulation
3. Communicate results and wrap up

*A person who facilitates change and provides subject matter **expertise**; someone who provides **advice**.*

Consultant (noun):

Expert, experience, experiential, and experiment -- common Latin root -- experire, meaning to try, to test, to prove.

*A consultant, then, is above all else empirical, that is, **willing to try things to see what happens**.*

A Consultant Wears Many Hats Over the Life of a Project



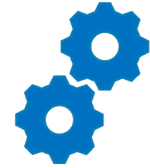
Define Scope

Define scope and understand the key questions that drive the answer



Develop Workplan

Develop a workplan to keep the team on track



Create Methodology

Create a methodology to (dis)prove the hypotheses



Ensure Accuracy

Ensure accuracy/attention to detail to solidify quality and credibility



Communicate Proactively

Build in regular communication with all stakeholders to gain allegiance before the final meeting



Manage the Client

Manage the client – find the decision maker; manage the scope; be aware of the politics

Consultant = Problem Definer

The Project Proposal Should Define Scope



Define Scope



Components of the Proposal

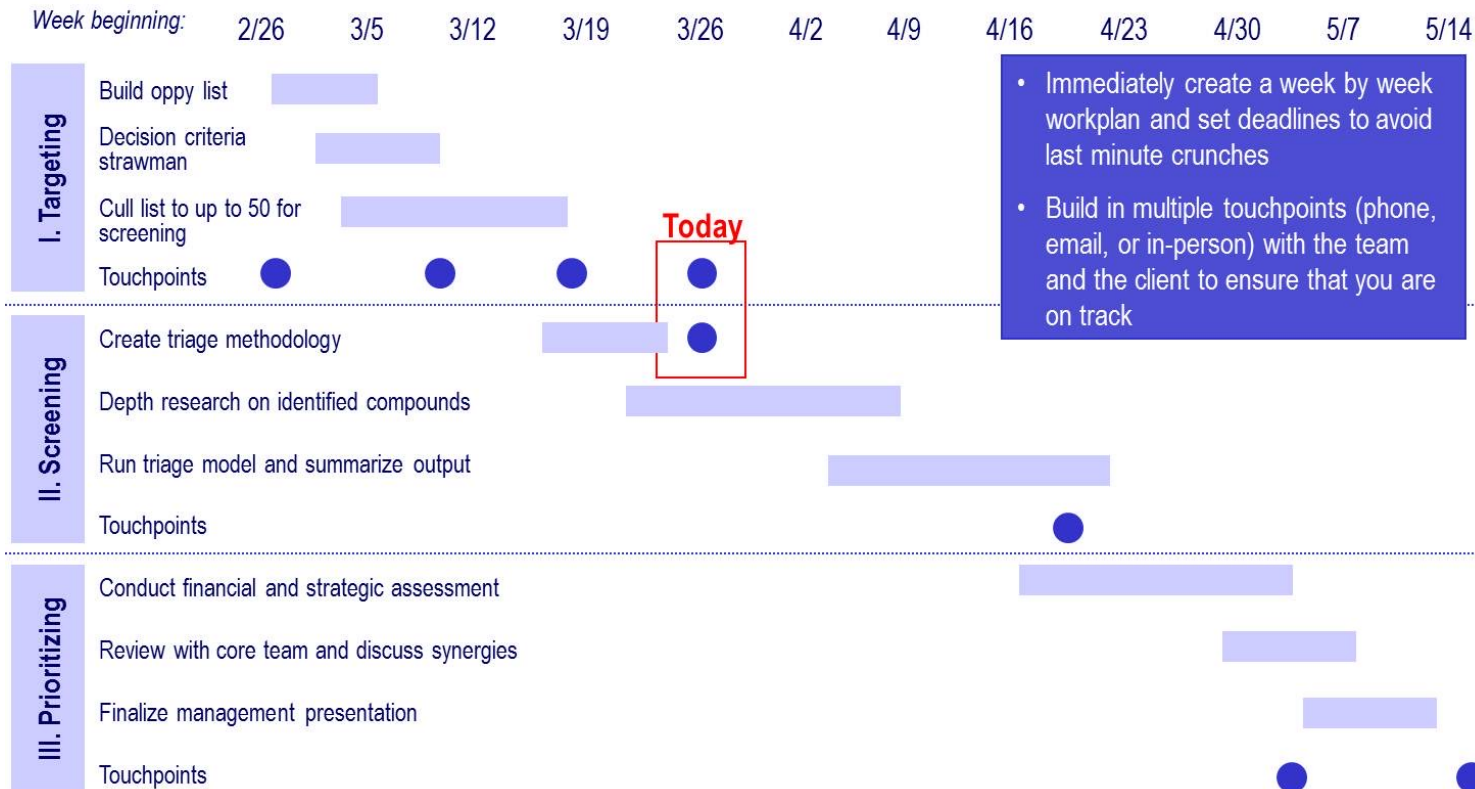
- ✓ Question Being Answered
- ✓ Scope of the Analysis
- ✓ Methodology to be Deployed
- ✓ Timelines
- ✓ Deliverables
- ✓ Price

Consultant = Project Manager

With Scope Defined, the Next Step is to Develop a Workplan



Develop Workplan



- Immediately create a week by week workplan and set deadlines to avoid last minute crunches
- Build in multiple touchpoints (phone, email, or in-person) with the team and the client to ensure that you are on track

Consultant = Data Searcher / Creator

Analytics Ultimately Rely on Solid Research & Data



Create Methodology

Primary Research

- Use primary research to confirm/refute hypotheses and fill info gaps
- Plan research as early as possible as it takes time to schedule interviews
- Good sources of primary research:
 - University Faculty
 - Your Clients
 - Physicians involved in research (use PubMed as a source)
 - Industry experts (use publications as a source)
 - Equity analysts

Secondary Research

- Ask clients for any research they currently have
- Use additional secondary research to “become an expert” on the space as quickly as possible – Financial, Clinical, Strategic information of all kinds
- Ensure information is reliable
 - Reputable sources
 - Recent information
- Be creative as data can come from various sources

Consultant = Thought Process Organizer

A Framework Helps Guide the Team Towards the Answer



Create Methodology

- **A client** wants to evaluate potential investments in hospice, outpatient infusion or veterinary
- Potential methodology: Determine important attributes of an attractive product (bucketed into categories – e.g., Clinical Rationale, Financial Rationale, Strategic Rationale, etc.) and then quantify as possible (see example below)
- Ensure client buy-in for all of the criteria and weighting/metrics so that results cannot be disputed

| Example Attributes/Criteria | Example Metric | | | | | Weight |
|---|----------------|--------------------|----------------|------------------|---------------|--------|
| • Clinical – how likely is clinical success of this drug? | 1 Low | 2 Low / Med | 3 Med | 4 Med / High | 5 High | 10% |
| • Financial (Revenue Proxy) – how large is the patient population? | 1 Small | 2 Small / Med | 3 Med | 4 Med / Large | 5 Large | 50% |
| • Risk - How long would it take to bring our product to market (time value of \$\$) | 1 6+ years | 2 5-6years | 3 4-5 years | 4 2-3 years | 5 <2 years | 10% |
| • Strategic – does the product support current market relationships? | 1 Limited | 2 Limited / Med | 3 Med | 4 Med / High | 5 High | 30% |

Consultant = Quality Controller

Accuracy is Critical for Credibility



Prevalence of Diabetes in the U.S.

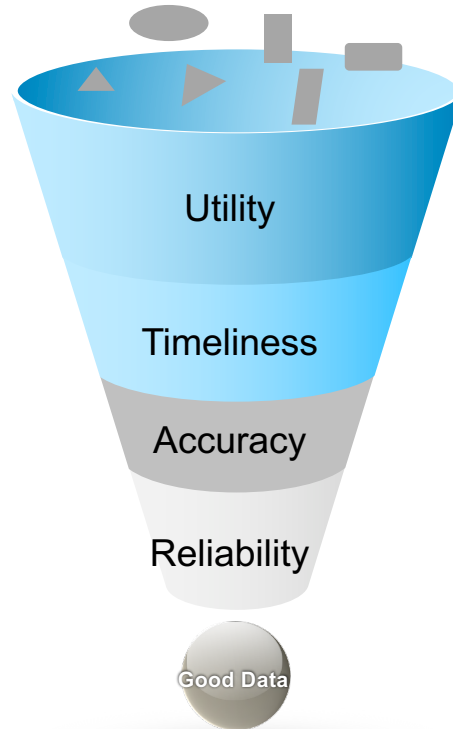
Bad Data

Prevalence of diabetes in the Uzbekistan

In 1968, 9.4M Americans were diagnosed with diabetes

Of a nursing home sample, 46% of patients had diabetes

Source: Shadyvale Nursing Home Website



Good Data

Prevalence of diabetes in the U.S.

NHANES 2018 study found that 7% of the population has diabetes

10.5% of all men aged 20 years or older have diabetes

Source: New England Journal of Medicine

Consultant = Storyteller

The Intended Audience Determines the Presentation Flow



Communicate Proactively

If your audience ...

- Clearly understands the business situation and your approach, or
- Agrees with your conclusions, or
- Is impatient, or
- Is an executive with little time

... Then use ...

Top-Down
(Inductive)

- Prepare for a more formal presentation
- Focus on conclusions
- Use large fonts, less text
- Create a thin deck (<10 slides)

If your audience ...

- Needs to be educated
- Considers your conclusions controversial, or
- Is detail-oriented/methodical

... Then use ...

Bottom-Up
(Deductive)

- Prepare for an “across the table” discussion
- Focus on the key underlying assumptions that drive the conclusions
- Create a moderate summary (~25 slides) with appendix support of key assumptions

Consultant = Relationship Manager

Client Satisfaction Requires High Attention



Manage the Client

Potential Client Management Issue

- A client has multiple competing priorities and your project is not their “whole world”
- With each new touchpoint, they need to be reminded about what had come before and yet would always be expecting the final answer, even during “interim” discussions

How It Can Be Managed

Leverage your relationships, strength of analysis & communication:

- Have key players validate results before the meeting with executives to ensure support during the meeting
- In the first few minutes of a new meeting, quickly refresh what progress and decisions had come before and what the purpose of today’s meeting is
- Consistently tie these decisions and location in the progress back to the key questions to demonstrate how today’s touchpoint ultimately impacts the answer they care about
- Clearly lay out the next steps to preempt questions
- Put everything in writing and get their responses in writing

Lessons Learned

1. Understanding the varied role of a consultant can help your teams run smoother and ensure that you are exceeding the expectations of your clients
2. Question everything constantly in order to get you to the root cause of issues ... always ask, “But why? But why?”
3. Plan early in order to avoid a crunch at the end of the term
4. Ultimately, clients rely on you for your expert opinion. You’ll only feel comfortable engaging in the conversation if you know your technology, market, competition, business models and financial valuation drivers inside and out (hence the “**expert**”)
5. Don’t be afraid of failure. Every experience is a learning opportunity
6. Have Fun!

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Overview of the Project

Situation

- Company X has the opportunity to pursue a long-acting version of prednisone, which is a steroid used to treat morning stiffness associated with rheumatoid arthritis (RA). Company X has absolutely no experience in the RA market and has no assets in rheumatology generally

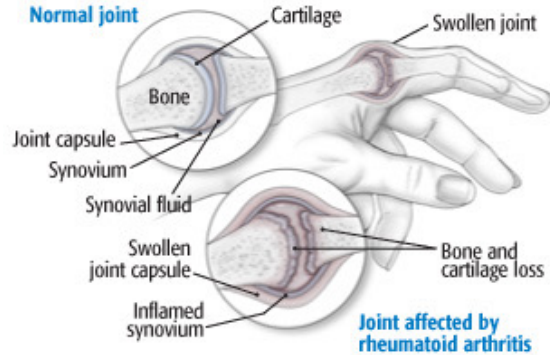
Complication

- The company has many potential development opportunities and is not sure if they should pursue this long-acting steroid or something else. They would only pursue this opportunity if they believe they can make \$200 million in topline U.S. peak year revenue

Question

- Should company X pursue this development opportunity of a long-acting steroid?
- Calculate the \$ opportunity (Back of the Envelope!) and summarize why or why not in 3 bullet points

Rheumatoid Arthritis (RA) Is An Autoimmune Disease Characterized By Chronic Inflammation And Joint Destruction



Criteria to determine if patient has RA

Morning Stiffness

Simultaneous swelling or fluid around three or more joints

At least one swollen area in the wrist, hand, or finger

Symmetric arthritis

Rheumatoid nodules

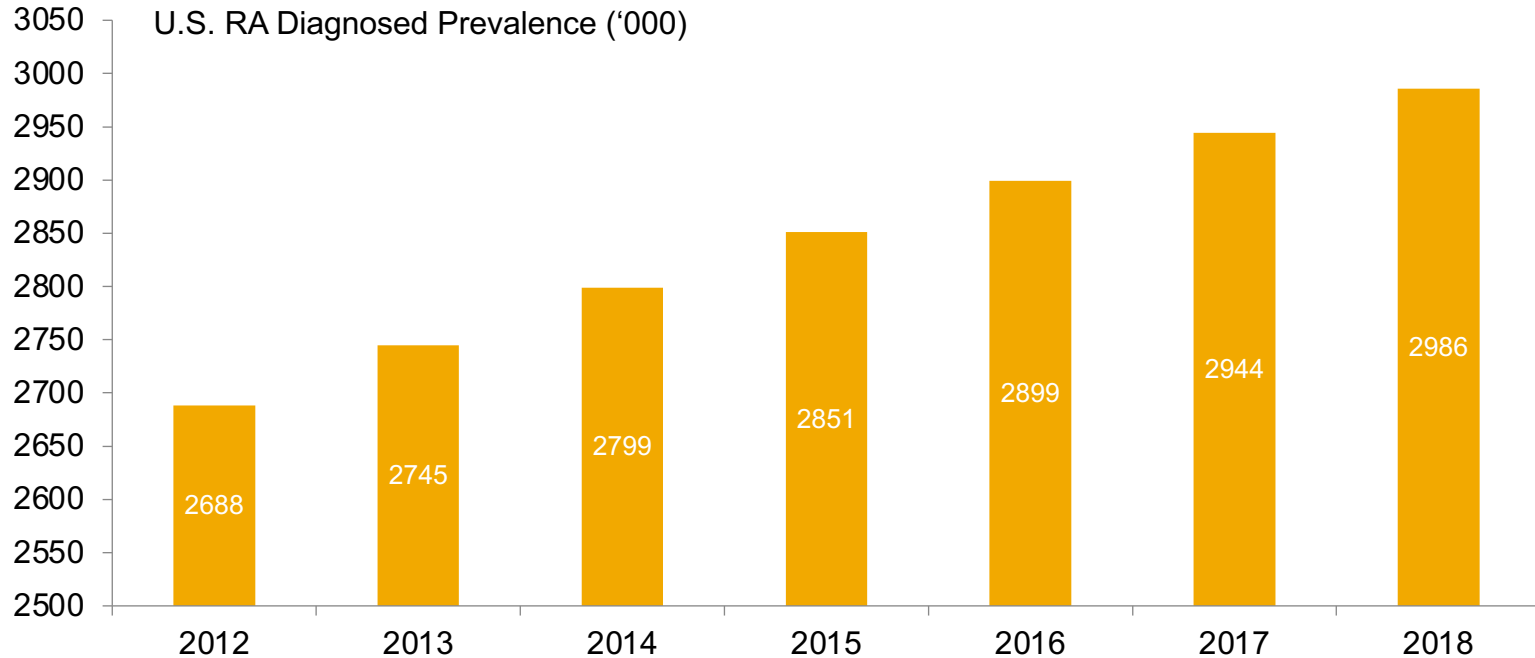
Abnormal amounts of serum rheumatoid factors in the blood

X-ray changes in the hands/wrists

RA Overview

- RA is a degenerative, inflammatory disease where a chronic autoimmune response attacks the lining of joints (synovium), ultimately leading to joint destruction
 - Multiple joints can be affected, usually at least 2 or 3 different joints are involved, often in a symmetrical pattern
 - RA most often affects the smaller joints, such as those of the hands, feet, wrists, elbows, knees or ankles. However, larger joints such as the shoulders, hips and jaw may also be affected
- RA causes gradual joint erosion and eventually loss of motion and joint deformation
- Common symptoms include significant pain and inflammation of the joints, fever, weight loss, fatigue, and morning stiffness
 - Symptoms may vary in severity and may alternate with periods of remission

U.S. Diagnosed RA Prevalence Is Close To 3M Patients Growing At < 2%



**Assume "Today"
is July 2018**

Diagnosis Of RA Involves A Combination Of Symptomatic And Clinical Criteria

JOINT DISTRIBUTION (0-5)

| | |
|--|---|
| 1 large joint | 0 |
| 2-10 large joints | 1 |
| 1-3 small joints (large joints not counted) | 2 |
| 4-10 small joints (large joints not counted) | 3 |
| >10 joints (at least one small joint) | 5 |

SYMPTOM DURATION (0-1)

| | |
|----------|---|
| <6 weeks | 0 |
| ≥6 weeks | 1 |

ACUTE PHASE REACTANTS (0-1)

| | |
|--|---|
| Normal C-Reactive Protein (CRP) <u>AND</u> normal Erythrocyte Sedimentation Rate (ESR) | 0 |
| Abnormal CRP <u>OR</u> abnormal ESR | 1 |

≥6 = definite RA

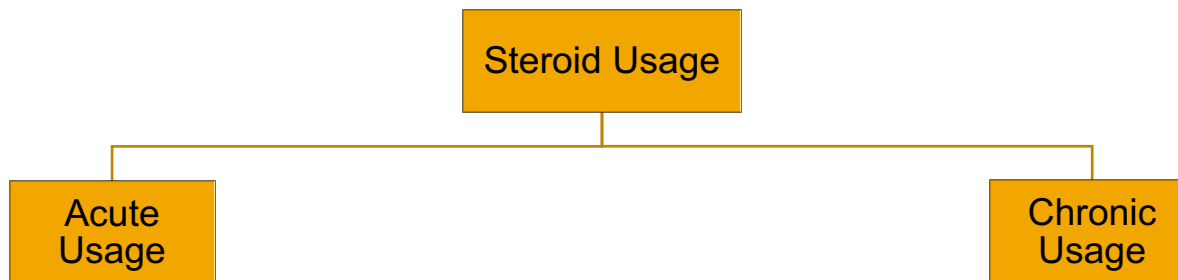
What if the score is <6?

Patient might fulfil the criteria...

→ Prospectively over time (cumulatively)

→ Retrospectively if data on all four domains have been adequately recorded in the past

Steroids Are a Mainstay of Treatment for Both Acute & Chronic Patients



- In order to get the disease under control, steroids may be used to manage “flares”
- Published guidelines suggest 15mg/day of steroids for up to one month (4 weeks) for acute therapy for a flare

“The drug is used [as] early onset [therapy] to establish control quickly and as bridge therapy to biologics.”

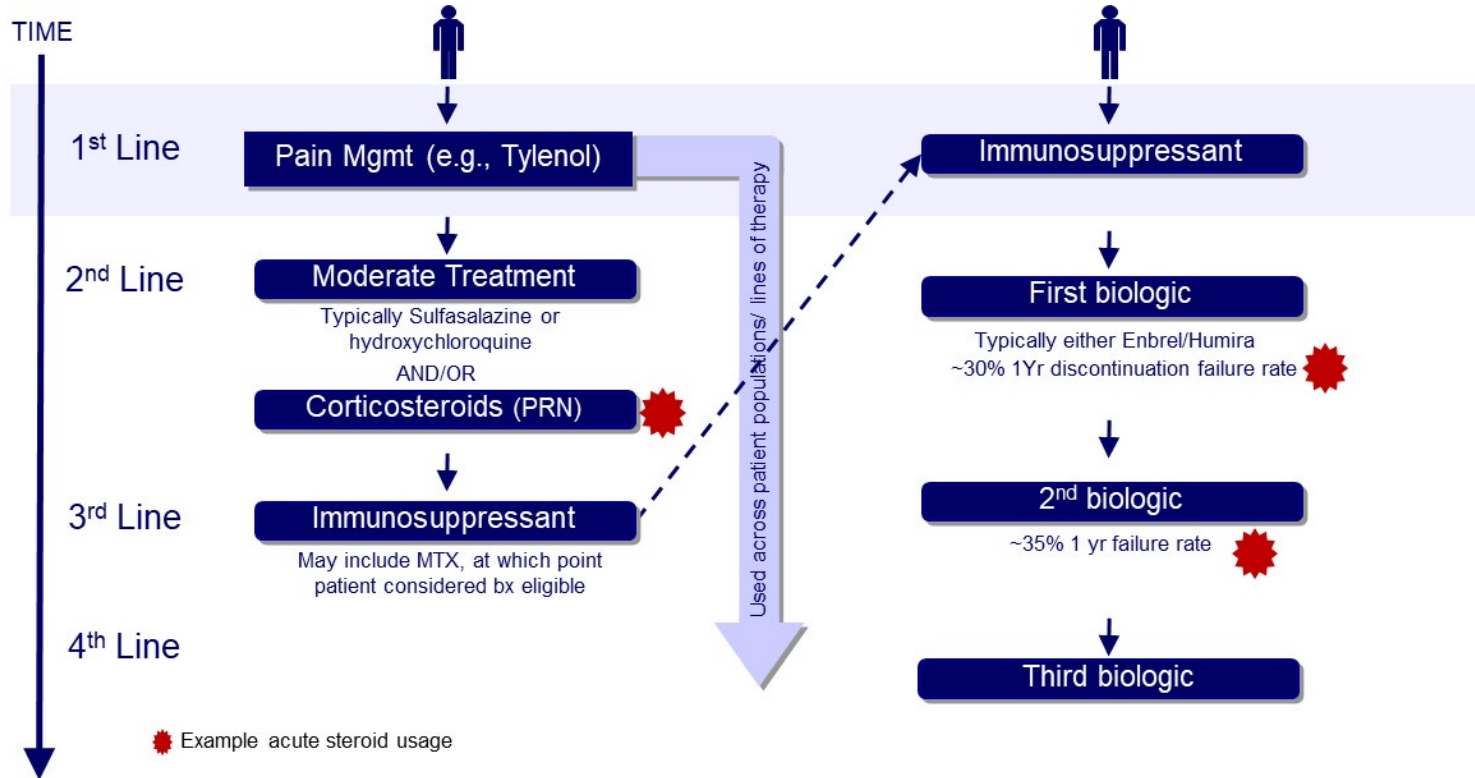
- Rheumatologist, CT

- For some RA patients, it is not possible to stop steroid use as their background treatment is not fully managing their disease activity
- Average dosing is about 5 mg/day indefinitely

“Those are normally resistant patients who have never responded fully to immunosuppressant therapy. They may have gone on to a biologic even, but they have a little bit of steroid added in.”

- Rheumatologist, UK

Acute Steroid Usage Is Commonly Used To Get A Flare Under Control, Such As When Biologics “Fail”



Chronic Steroids Are Used When It's Not Possible to Prevent Disease Flares Without the Constant Use of Steroids

Primaries say
~20% Chronic

- Physician interviews (n=20) say 30-40% of patients on steroids at a given time, and 50% are chronic vs. 50% are acute. So a total of 20% of RA patients (40% on steroids and 50% of those are chronic) are on chronic steroids.

2nd Source 1:
~23% Chronic

- Datamonitor says a total of 30% of U.S. RA patients on steroids at a given point, and ~25% are acute and ~75% are chronic. So this means that ~23% (30% of RA patients are on steroids X 75% chronic) of RA patients are on chronic steroids.

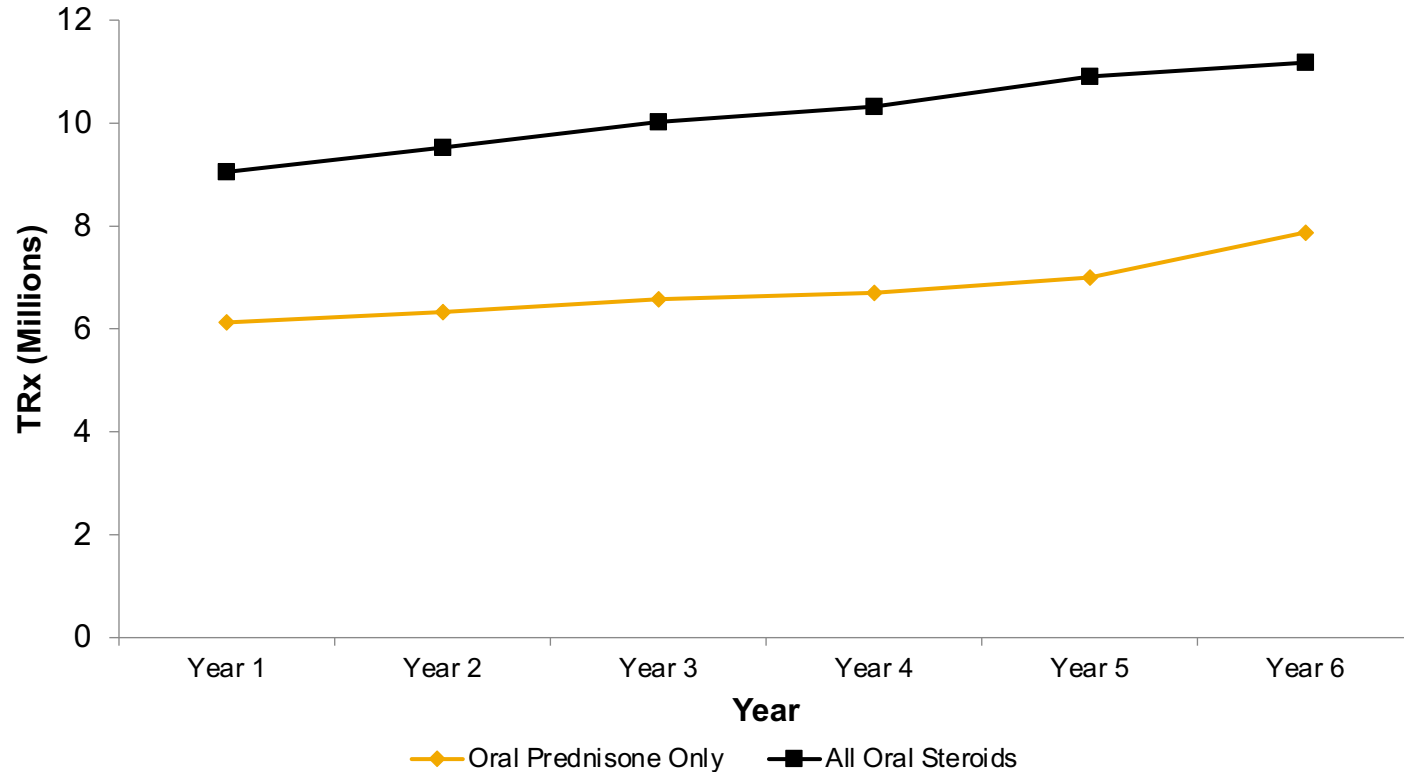
2nd Source 2:
~10% Chronic*

- National Data Bank of Rheumatic Diseases studied 12K U.S. patients longitudinally, finding:
 - 66% of RA patients on steroids at some point in the course of their disease
 - 40% of RA patients are on steroids “currently”
 - Of the current steroid use, about 75% are on acutely and 25% are on chronically

*This study defined “chronic” as 5 years of therapy, which is longer than our definition and thereby deflates the size of the market

Total Prescriptions For Oral Prednisone Are Increasing 7%

RA Oral Steroid Use In The US (Total Prescriptions)



Steroids Are Extremely Effective, But Their Use Is Limited Due To Side Effect Concerns; They Also Don't Affect Morning Stiffness Well

| Unmet Need | Examples |
|--|--|
| Significant safety concerns at high doses (e.g., > 15-20mg/day for extended periods) | <ul style="list-style-type: none">• Weight gain• Cardiac issues• Gastrointestinal issues• Blood issues• Etc. |
| Timing of action | <ul style="list-style-type: none">• Steroids are taken during the day to reduce inflammation, but some of the hardest times for RA patients are in the morning when they first wake up, when the effect has worn off |
| Efficacy | <ul style="list-style-type: none">• Not an unmet need; steroids work well |
| Cost | <ul style="list-style-type: none">• Not an unmet need; steroids are generic |

“If they have milder disease we try not to use corticosteroids because they often are not disabled enough to justify the risk of a corticosteroid.”

- Rheumatologist, PA

“Even if you take steroids before you go to bed, RA patients wake up with morning stiffness and then need a big dose to get started with their day.”

- Rheumatologist, CA

“The problem with steroids is not their lack of efficacy, it's their side effect profile.”

- Rheumatologist, CT

Product X Would Address The Unmet Need Of Improved Morning Stiffness Control

Description

- Product X is a controlled release prednisone
- Taken at bedtime, Product X features a unique hydrophilic shell that delivers low-dose prednisone 4-6 hours later, delivering steroid therapy at the physiologically optimal time ... in the morning

Indication

- Treatment of moderate to severe, active rheumatoid arthritis in adults particularly when accompanied by morning stiffness; to be used in either an acute or chronic treatment regimen

Pricing

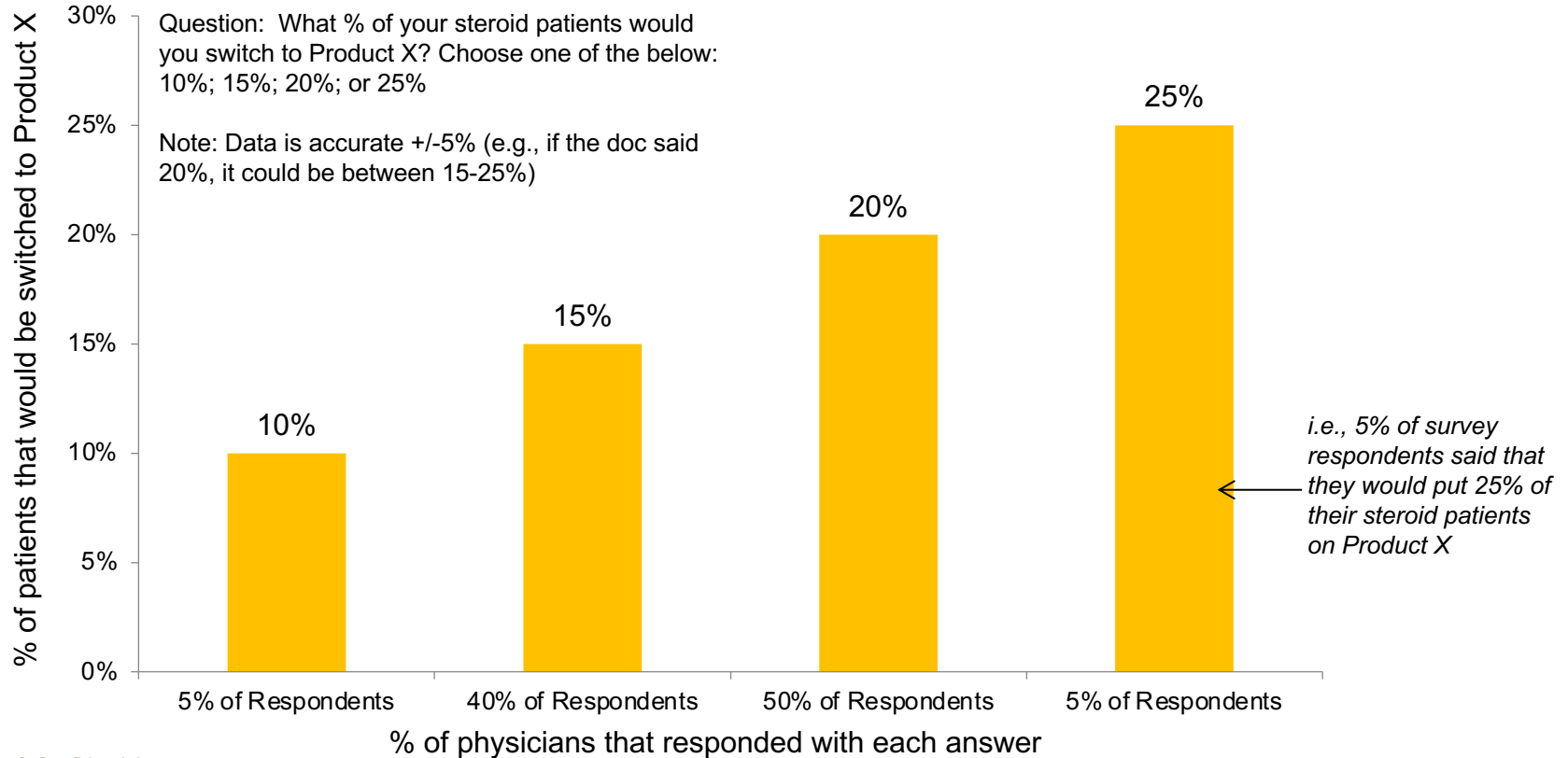
- \$5 per 5mg pill
- 20 pills in a bottle

Timing

- Will launch February 2019 in the U.S.

Assume “Today” is July 2018

In A Survey About Product X, Below Is The % Of Patients That Would Receive The Drug



The Key For Uptake Will Be Getting Physicians To Write “Product X” Instead of Their Habit Of Writing “Prednisone”

When you write the prescription, you just write prednisone and you don't choose a brand name?

“That’s correct. I just write ‘prednisone’.”

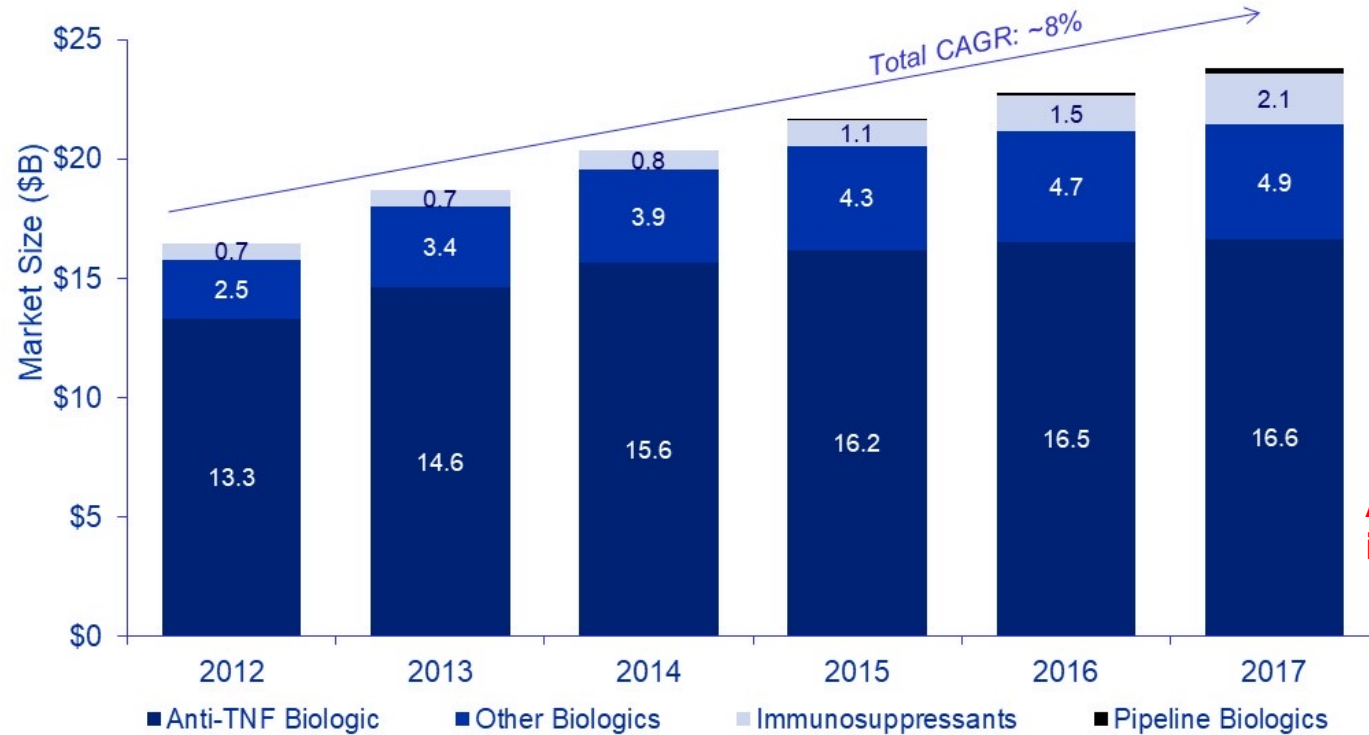
- Rheumatologist, IL

When you write a prescription, do you just write “prednisone”?

“That’s right. It’s generic. I don’t even know if you could do that or if there are restrictions on the patient’s formulary. It depends on what kind of generic prednisone the pharmacy that the patient goes to has. Most of the time we don’t even know what kind they get.”

- Rheumatologist, NY

The RA Market Is Relatively Price-Insensitive Given The Use Of Expensive Biologic Agents In Moderate-To-Severe Disease



It Is Not Anticipated That The Pricing For Product X Would Lead To Payer Hurdles Unless Usage Hits A “Critical Mass” Level

Would you put in a prior authorization so that physicians need to get permission to use product X?

“There is a cost to having a prior authorization. That cost we figure is about \$25-30 [per claim] – when we need an active intervention to take a call and send the physician a fax and get it back. Unless they price [Product X] ridiculously, it will probably just be handled by being put on the third tier [which is \$40-50 copay per month]. ”

- Pharmacy Director in a U.S. PBM

Would you put in a prior authorization so that physicians need to get permission to use product x?

“We do prior auths on anything over \$800-1000 per month; drugs that may be abused; drugs that could be contracted, which exclude things like weight loss agents, sexual dysfunction, etc. Those are prior auth. Clinical efficacy has nothing to do with tiering anymore. It purely comes down to cost ... [Product X] would probably be Tier 3 [which is \$100 per month copay].”

- Pharmacy Director is a U.S. Commercial Plan

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Discussion of Team Results