

# PDA Case Study

## Biosimilar of Biologic Treatment for Rheumatoid Arthritis

October 2023



## Pharma situation

**ABC Biopharma:** Launching a biosimilar of biologic treatment for rheumatoid arthritis and other autoimmune diseases once innovator patents expire in 2025 (PRODUCT NAME: Bioxeatin)

**Innovator product:** Re-usable autoinjector with wireless connection (reminders, injection history: data can be shared)

**Treatment:** Self-administration at home. Weekly dosing



### Objective

To develop a Patient Support Programme (PSP), incorporating specific behavior change techniques, combined with real-time usage data from the connected device to increase patient adherence to Bioxeatin.

Non-adherence rates are high in RA. Incorporating the connected device in the PSP will distinguish ABC Biopharma from their competitors.

## Challenges for people living with rheumatoid arthritis

*Autoimmune and inflammatory disease that attacks healthy cells causing painful swelling in affected parts of the body<sup>1</sup>*

### **Managing impact of unpredictable symptoms**

- swollen joints
- joint pain
- loss of strength
- fatigue
- trouble sleeping

### **Identity and psychological well-being**

- Acceptance
- Loss of status and potentially earnings
- Appearance
- Fertility (younger patients)
- Relationships and sex
- Difficulty asking for and accepting help
- Depression and frustration



## Social and psychological impact of rheumatoid arthritis

- Depression and anxiety are more common if you have RA
- 17% of people living with RA also have clinical depression<sup>1</sup>
- 60-75% of people living with RA also have another co-morbidity (e.g., cardiovascular disease, diabetes)<sup>2</sup>
- After diagnosis, 45% of people with RA had to stop working<sup>3</sup>

## Patient persona - meet Rita

- Rita was diagnosed with rheumatoid arthritis (RA) 5 years ago. She works as a teaching assistant at a local primary school and tries to control her RA through a combination of exercise and medication.
- Occasionally, Rita gets very frustrated and angry by her painful joints and restrictions on her mobility which limit the time she can spend playing with her grandchildren, and also means she struggles sometimes at work.
- Although Rita tries to maintain a good treatment routine, she's worried about remembering to take her Bioxeatin (weekly injection). She also doesn't feel that she completely understands her RA and its symptoms which are so unpredictable; or the role that Bioxeatin might play in managing those symptoms
- Rita has previously had a difficult relationship with both her GP and hospital consultant who she feels do not understand the impact that the RA has on her life. She has never sought out any support for her RA.

## Personal Information

**Age:** 58

**Gender:** Female

**Employment:**

Full-time teaching assistant

**Family:** Married. 2 children and 4 grandchildren

**Years since diagnosis:** 5

**Comorbidities:** Hypertension

**Treatment history:** Methotrexate and occasional courses of corticosteroids; has just been prescribed Bioxeatin.

**Bioxeatin:** A biosimilar of a biologic treatment used to improve moderate disease activity in RA. Delivered weekly through a re-usable auto-injector with wireless connection (reminders, dosing history; data can be shared)



# Workshop 1

## Understanding patient behavior and experience

## Workshop 1: Understanding patient behavior and experience

1. Use a behavior framework to understand adherence challenges to Bioxeatin for Rita
2. What broad intervention approaches (e.g., channels, content, data) would be effective for the adherence challenges you have identified?
3. If time, suggest behavior change techniques (BCTs) you might use to address the adherence challenges you have identified?

## Workshop (Part A): Understanding patient behavior and experience

1. Use a behavior framework to understand adherence challenges to Bioxeatin for Rita. Work with your group to describe these adherence challenges on the COM-B model.



# Workshop 1 (Part A): Applying the COM-B framework

## The COM-B model:

- The COM-B model sets out the groups of factors (Capability, Opportunity, Motivation) that influence the performance of a given behavior.
- ***Describe the challenges that might impact adherence to Bioexatin for Rita***



### GROUP WORK - The COM-B model:

- The COM-B model sets out the groups of factors (Capability, Opportunity, Motivation) that influence the performance of a given behavior. ***Describe the challenges that might impact adherence to Bioxeatin for Rita***



## Workshop 1 (Part B): Understanding patient behavior and experience

2. What broad intervention approaches (e.g., channels, content, data) would be effective for the adherence challenges you have identified?
3. If time, suggest behavior change techniques (BCTs) you might use to address the adherence challenges you have identified?

# Workshop 1 - STIMULUS: behavior change techniques (BCTs)

- BCTs are theory-based methods for changing one or several aspects of behavior
- The ‘active ingredient’ of a behavior change intervention
- There are 93 BCTs
- Arrived at through international and interdisciplinary consensus
- Reported in a comprehensive taxonomy, organized into hierarchical clusters, that is ever evolving
- **CAN BE DELIVERED VIA MANY DIFFERENT MEANS/MODES**

BCT Taxonomy (v1): 93 hierarchically-clustered techniques			
Page	Grouping and BCTs	Page	Grouping and BCTs
1	<b>1. Goals and planning</b>	8	<b>4. Comparison of behaviour</b>
1.1. Goal setting (behaviour)	8.1. Demonstration of the behavior	16	<b>11. Antecedents</b>
1.2. Problem solving	8.2. Social comparison	11.1. Restructuring the physical environment	
1.3. Goal setting (intention)	8.3. Information about effort approval	11.2. Restructuring the social environment	
1.4. Action planning	9	11.3. Avoidance/reducing exposure to cues for the behavior	
1.5. Reverse behavior goal(s)	<b>7. Associations</b>	11.4. Distraction	
1.6. Discrepancy between current behavior and goal	7.1. Associations	11.5. Adding objects to the environment	
1.7. Reverse outcome goal(s)			
1.8. Behavioral contract			
1.9. Commitment			
3	<b>2. Feedback and monitoring</b>		
2.1. Monitoring of behavior by others without feedback			
2.2. Feedback on behavior			
2.3. Self-monitoring of behaviour			
2.4. Self-monitoring of outcome(s) of behaviour			
2.5. Monitoring of outcome of behavior without feedback			
2.6. Biofeedback			
2.7. Feedback on outcome of behavior			
5	<b>5. Social support</b>		
5.1. Social support (verbal)			
5.2. Social support (practical)			
5.3. Social support (emotional)			
6	<b>6. A. Shaping knowledge</b>		
6.1. Instruction on how to perform the behavior			
6.2. Information about antecedents			
6.3. Attribution			
6.4. Behavioral experience			
7	<b>7. Natural consequences</b>		
7.1. Information about the consequences			
7.2. Balance of consequences			
7.3. Information about social environmental consequences			
7.4. Monitoring of emotion consequences			
7.5. Anticipated regret			
7.6. Information about environmental consequences			

  

BCT Taxonomy (v1): 93 hierarchically-clustered techniques			
Note for Users			
The definitions of Behavior Change Techniques (BCTs):			
i)	contain verbs (e.g., provide, advise, arrange, prompt) that refer to the action(s) taken by the person/s delivering the technique. BCTs can be delivered by an 'interventionist' or self-delivered		
ii)	contain the term 'behavior' referring to a single action or sequence of actions that includes the performance of <b>wanted</b> behavior(s) and/or <b>inhibition</b> (non-performance) of <b>unwanted</b> behavior(s)		
iii)	note alternative or additional coding where relevant		
iv)	note the technical terms associated with particular theoretical frameworks where relevant (e.g. including implementation intentions)		

  

No.	Label	Definition	Examples
<b>1. Goals and planning</b>			
1.1	<b>Goal setting (behavior)</b>	Set or agree on a goal defined in terms of the behavior to be achieved <i>Note: only code goal-setting if there is sufficient evidence that goal set as part of intervention; if goal unspecified or a behavioral outcome, code 1.3. Goal setting (outcome); if goal defines a specific context, frequency, duration or intensity for the behavior, ggg code 1.4. Action planning</i>	Agree on a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal  Set the goal of eating 5 pieces of fruit per day as specified in public health guidelines.
1.2	<b>Problem solving</b>	Analyse, or prompt the person to analyse, factors influencing the behavior and generate or select strategies that include overcoming barriers and/or increasing facilitators (includes <b>Relapse Prevention</b> and <b>Coping Planning</b> ) <i>Note: barrier identification without solutions is not sufficient; if the BCT does not include analysing the behavioral problem, consider 12.8. Avoidance/changing exposure to cues for the behavior, 12.1, Restructuring the physical environment, 12.2, Restructuring the social environment, or 11.2, Reduce negative emotions</i>	Identify specific triggers (e.g. being in a pub, feeling anxious) that generate the behavior and develop strategies for avoiding environmental triggers or for managing negative emotions, such as anxiety, that motivate drinking  Prompt the patient to identify barriers preventing them from starting a new exercise regime e.g., lack of motivation, and discuss ways in which they could help overcome them e.g. going to the gym with a buddy

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## Workshop 1 (Part B): STIMULUS: BCT CLUSTERS: the 93 BCTs cluster into 16 groups

1. GOALS & PLANNING
2. FEEDBACK & MONITORING
3. SOCIAL SUPPORT
4. SHAPING KNOWLEDGE
5. NATURAL CONSEQUENCES
6. COMPARISON OF behavior
7. ASSOCIATIONS
8. REPETITION/SUBSTITUTION
9. COMPARISON OF OUTCOMES
10. REWARD & THREAT
11. REGULATION
12. ANTECEDENTS
13. IDENTITY
14. SCHEDULED CONSEQUENCES
15. SELF BELIEF
16. COVERT LEARNING

## Workshop 1 (Part B) – Group Work

Adherence challenges	
Broad intervention approach (e.g., channel, content, data)	
Behavior change techniques (BCTs)	

# Workshop 2

## Value Creation with Smart Devices and Digital Solutions

## Workshop 2: Please identify relevant value drivers for stakeholders

Patients	Healthcare professionals
Caregivers	Healthcare systems



## Workshop 2:

Do we need a capture template for the 2<sup>nd</sup> bullet point:

How to link patient engagement and success metrics?

# Workshop 3

## Regulatory and compliance challenges

Market	Brand level of PSP	Typical channels implemented	Health authority approval needed	Anonymized PSP data can be analyzed locally and globally with patient consent	Patient data can be stored outside the local country in line with regulations?	Enrolment process/consent √=prescribed patient is allowed to self-enrol without HCP signature  Consent collection methods indicated below	PSP precedent
UK	PSP branding must not match product branding, brand name can be used sparingly	Web Apps Calls SMS , emails Nurse Support	* Unless product is in risk category	✓	✓	✓ – Any form of consent collection permitted	<a href="https://www.dupixentmyway.co.uk/atopicdermatitis/dupixent-support-and-resources">https://www.dupixentmyway.co.uk/atopicdermatitis/dupixent-support-and-resources</a>
Germany	PSP branding must not match product branding, brand name can be used sparingly	Web Apps Calls SMS emails Nurse Support	*	✓	✓	✓ – Any form of consent collection permitted	<a href="https://www.abbvie-care.de/">https://www.abbvie-care.de/</a>
Italy	PSP branding must not match product branding, brand name can be used sparingly	Web Apps Calls SMS emails Nurse Support	*	✓	✓	Paper consent is most frequently implemented, to collect HCP signature	<a href="https://www.abbviecare.it/">https://www.abbviecare.it/</a>
Spain	PSP branding must not match product branding, brand name can be used sparingly	Web Apps Calls SMS emails Nurse Support	Recommended	✓	✓	✓ – Any form of consent collection permitted	<a href="https://abbviecare.es/">https://abbviecare.es/</a>
France	PSP branding must not match product branding, brand name can be used sparingly	strictly educational services, available for all patients and	✓ – 12 to 18 months	✓	Data held in market	Pharma Co not to have direct patient contact, for standard PSPs, even through third party	<a href="http://www.hemavie.fr">www.hemavie.fr</a> (unbranded – funded by BMS but developed/implemented by patient association with a PSP vendor)

# Workshop 4

## Global implementation consideration

## Workshop 4: Go To Market Strategy

Internal stakeholders	Key Roles	Actions

# Go to market strategy



## Topic 3: The Challenges

pda.org

### Workshop on the Case Study: Global Implementation Consideration

Moderators: Paul Upham, *Roche/Genentech* & Arnaud Guillet, *Biocorp*



#### *Mapping internal stakeholders – a participant activity*

- a. Create a list of stakeholders with key roles and what actions do you expect from them?
- b. Localization and Customization
- c. Training and Customer Support
- d. Legal and Compliance Approvals
- e. Customer Engagement Strategy