

Assessment B

Managing New Product Development

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DESIGN BRIEF FOR CHEMICAL DETECTOR SYSTEM

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Synopsis

As the NPD and Innovations Manager I have been tasked with creating a Product Design Brief.

The brief will be the touch point for all the company's managers, to include departments such as design & engineering, manufacture, finance, marketing, logistics etc.

As the company already manufactures electronic breathalyser systems, it wants to explore a new product in light of the coronavirus pandemic. The company sees great potential in developing a product that can meet both clinical and personal requirements for such virus detection.

The various managers will use the following information to review the new product design details and deliberate its contents.

Version Log:

<u>Date</u>	<u>Amended</u> <u>Made by:</u>	<u>Amendment</u> <u>Made:</u>	<u>Version</u> <u>Number</u>
03.09.2023	B Lessimore	Brief Created	1.0

Aesthetics & Ergonomics

When thinking about the aesthetics of a new product, it's important to factor in the pleasing qualities that define the product. The question is, what will impress the customer with their first impression of the product?

Will it be the:

- Colour
- Pattern
- Movement
- Size
- Shape
- Visual Weight
- Touch
- Feel

(BBC, 2023)

In terms of ergonomics, being successful in creating a device that gives our end user a comfortable, stress -free experience the following points need to be reviewed:

The Device	Weight	The device should be light enough to hold in one hand
	Shape	Should the shape of the device be thinner towards the bottom, creating a better area to hold?
	Surface Finish	Not too shiny that the user cannot hold for too long
	Grip	Allowance made for people with both a weak and strong grip, and Left or Right Hand?
	Strength	Strong enough to withstand a sudden drop
	Function Keys	Are the keys big enough, but not too big
	Key Layout	Are they easy to press if trying to use one hand?
	Key Labelling	Making this clear enough for all users
	Background, colour, contrast	Ensuring all 3 do not clash and are so bright that the user cannot use the display function
	Legibility	Ensuring the font is easy to read
	Any Other Considerations	?

(Gupta, 2003)

Advertising

Whilst not all advertising will be a direct cost, at this stage the company should be reflecting on the advertising of this product and the likely associated costs.

Below are some suggestions to work from:

- Editorial in Local or National Newspapers
- Social networking sites
- Product or web-based forums
- Trade Shows
- Website
- Local Governments Support

(Design, 2023)

Branding

Building a brand for our new product is the most practical step to cultivating the reputation we want with our audience, as a guide I have shown some points for discussion below, which can take place before the brand is created:

- Identifying our audience
- Research our competitors
- Define our brand's purpose and position
- Develop a personality and brand voice
- Create our brand story
- Pick a brand name
- Write a slogan
- Design our brand look and logo (May not be necessary if remaining with current company logo?)
- Integrate our brand into your business
- Don't be afraid to rebrand

(Adobe, 2023)

Care, Maintenance & Repairs

To ensure optimum care for the device, considerations such as below should be discussed:

- If the device is not going to be watertight then the user should never Immerse the device in water or other liquids
- Cleaning of the device could be carried out using maybe a soft cloth, slightly dampened.
- Never use aggressive cleaning agents, thinners, abrasive brushes on the device
- If at the design technical stage a power lead is introduced, a mention to unplug this when device is not being charged.
- If the device is cared for in this way, a timeline of when a service should be carried out should be noted.
- Repairs should be directed through the customer service team

(Laboratories, 2023)

Calibration

If the life cycle of the instrument is going to supersede 12 months, a review of how the test kit is calibrated should take place.

Some Considerations:

- Will there be a function within the menu to allow the user to carry out its own calibration?
- Should the results be uploaded to a main portal to verify the machine is functioning correctly?

Company Constraints

The most common constraints to factor into our brief is Money, Time & People

Money

Underfunding a product launch virtually assures failure.

- It's essential to keep a close eye on costs as we develop new products and services to avoid them spiralling out of control. The Finance department should:
 - estimate development costs in advance.
 - monitor spending throughout the development process.
 - introduce phased investment - e.g. release funds for each new development stage once the previous one has been successfully completed

Time

- It's Important to keep regular monitoring on the Gantt chart for deadlines and a member of the team should be appointed this duty.

People

- The most common complaints about resources are too few, wrong skills, and wrong experience. HR's involvement within this area would be greatly appreciated.

(Institute, 2023) (Info, 2023)

Cross Reference

Time Scale

Competition

With the unprecedented technological, economic, and social changes around us as business, we need to focus on a competitive strategy. It's a challenge for any business to impact the core audience they are aiming for, that's why it's so important we develop a strategy to give ourselves the edge over our competitors.

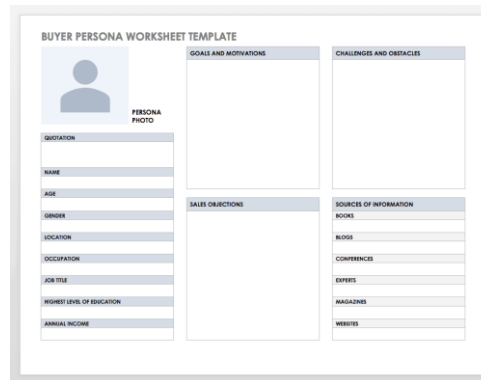
- It's important to establish and understand any current customer frustrations with similar products on the market - this could lead to better opportunities for the company and in turn could aid with:
 - Giving the best value
 - Setting the most competitive price

(Bhardwaj, 2022)

Customer

Following the initial research that has been carried out with Market Intelligence / Research, I would suggest the company looks to complete personas to identify the kind of market the company is hoping to break into. Whether that be customers or businesses.

I have included a template for completion:



The image shows a 'BUYER PERSONA WORKSHEET TEMPLATE'. It is a structured form for creating a buyer persona. On the left, there is a section for 'PERSONA PHOTO' with a placeholder icon. Below this is a 'QUOTATION' field. Further down is a list of demographic and professional details: NAME, AGE, GENDER, LOCATION, OCCUPATION, JOB TITLE, HIGHEST LEVEL OF EDUCATION, and ANNUAL INCOME. To the right of these details are four main sections: 'GOALS AND MOTIVATIONS', 'CHALLENGES AND OBSTACLES', 'SALES OBJECTIONS', and 'SOURCES OF INFORMATION'. The 'SOURCES OF INFORMATION' section is further divided into sub-sections: BOOKS, BLOGS, CONFERENCES, EXPERTS, MAGAZINES, and WEBSITES.

(Reference - Picture 1)

Circular Economy

The three principles of circular economy are:

- Eliminate waste
- Keep materials in use
- Regenerate natural systems

(MacArthur, 2023)

In cross referencing our main single-use item, the mouthpiece, if the company pursues it searches into bio-degradable plastics then it will begin to tackle the elimination of waste.

With the fact that up until now covid tests have been disposable and this device will step away from that, the main body of the device will be a much longer-term product in order of keeping the materials in use and regeneration of natural systems.

Cross Reference

- Materials

Documentation

Several documents should be considered throughout this project, to include:

- Product Design Brief
- Product Technical Specification
- BSI Standards
- Gantt Chart
- Legislative

Cross Reference

- Time Scale
- Standards
- Legal

Environment

Each environment will provide different scenarios to consider such as:

- Storage Temperature
- Usage Temperature
- Dust
- Water
- Extreme Weather Events
- Chemicals
- Shock

Funding

It's important to identify if there is any funding available towards this new project. I have referenced some options below for the finance department to further research:

- Business Wales Grants - [Grants | Business Wales \(gov.wales\)](#)
- Development Bank Wales - [Loans for Welsh businesses - Dev Bank \(developmentbank.wales\)](#)
- Powys County Council - [Grants and advice for new businesses - Powys County Council](#)

Legal & Intellectual Property

There are a variety of legal and business issues to address when launching a new product, as a minimum the following should be reviewed:

- The company should never assume that when discussing this new project that everyone will treat the details with the strictest of confidence. In the first instance a Non-Disclosure Agreement should be drawn up and issued to anyone involved
- Third Party venture with the local university Transfer Knowledge Programme needs some consideration with legal documents concerning the ownership of the new product.
- Manufacturing agreements need to be in place with potential new suppliers.
- Ensure product liability has been discussed.

Intellectual Property (IP)

The main types of IP the company needs to review are:

➤ **Trademarks**

- Unregistered – this could be considered if we use the current company brand and goodwill is built into it.
- Registered – This would need to be reviewed if the company is going to rebrand this product, alongside the trademark, which in themselves create both an asset and clearer right to enforce.

➤ **Patents**

- Patents will allow the company to ensure the invention of the device is protected before its released into the public domain.

➤ **Designs**

- Registered – The company could consider registering the design through the UK IPO – If this is an option to the company it's worth noting at this stage, its advisable to conduct a full clearance search before applying.
- Unregistered – Unregistered UK 'Design Rights' will rise automatically to protect certain shapes and configuration (3D) designs. However, its important to note Design Rights provide much less protection than Registered Designs

➤ **Copyrights**

- This is more in line with literacy, dramatic and musical & artistic work, as well as software/ databases and audio recordings.

➤ **Trade Secrets**

- There is no specific register for this but as mentioned in a previous element, its vital to ensure Non-Disclosure Agreements are in place.

(Salmon, 2021)

Life in Service & Performance

The company would need to establish the expected number of tests that the device will be able to achieve v's the accuracy of the tests.

To possibly extend the life of the device, a suggestion could be made to replace the sensors after a given amount of time.

The performance of the device will be very dependent on factors mentioned below as an example:

- Exposure to extreme heat
- Exposure to extreme cold
- Failure to ventilate the sensor after use with condensation (rust)

(Testing, 2018)

Materials

The Device

- The outer shell of the casing needs to be robust and able to withstand various impacts. A hard injection moulded plastic possibly?
- This is not classed as a single use product for circular economy purposes but would keep in line with 'Material in Use'.

The Mouthpiece

Different considerations should be made with the mouthpiece as this will be classed as single use. On looking into this further I have discovered the following for review:

- A company called FKUR offer a 100% biodegradable water -soluble plastic for injection moulding (or extrusion if required)
- The granules are offered with a controllable water dissolution temperature of 5-70°C
- The material is called Terrasol, the raw granules include high crystallinity which lends itself to less shrinkage to the finished product.
- After full contact with water any products made from Terrasol with dissolve completely and without any residue.

(FKur, 2023)

Manufacturing Facilities

Discussions to be had around the following:

- Will the current facilities be able to accommodate this new production?
- What about warehouse space for the WIP/ Final product?
- Additional Employee's will mean further car parking spaces.
- If an additional site is required, considerations will need to be made for locality, expansion and how will the current company set up accommodate this?

Market Constraints

The company should make considerations against market constraints in that this could factor in production limitations, including but not limited to competitors, consumers and the laws of supply and demand.

As examples the following should be included:

- **Size of market** – Making sure the company doesn't offer the product with relatively little awareness, making the market rather small. In order to expand its reach and improve the revenue the right amount of resources should be channelled into marketing to broaden the customer base
- **Competitors** – Protecting the company from competitors and their potential gains on the market share. Further innovation can help with ensuring our company stays competitive. Competition can also benefit the consumer. Market research can help to understand what consumers want and it's also a guide for future developments.
- **Consumer** – The behaviours of consumers have a large impact on our business processes and production. The demand for this product could be

a constraint both for when its high and low because this will determine production levels throughout both times.

(Indeed, 2023)

Packaging

Before placing an order for packaging there are certain factors that need to be taken into account:

- Quality and functionality
- Size, Shape and Design
- Pricing
- Will the packaging store well
- Long-term sustainability
- Printing
- Will the packaging travel well
- Stack ability on Pallets
- Wrapping

Politics

It's recently been reported by the former public health minister Lord Bethell that he fears the UK hasn't learnt lessons from coronavirus and health resources are in a worse shape now than before the pandemic.

- He was particularly struck by how the pandemic had exacerbated the already limited resources of the NHS
- He said the government had failed to move on from a hospital-based method of care, and should have been more pro-active in trying to identify the disease earlier.
- And now it's a case of how do we improve the happiness of people, as there are now tens of thousands of people in the country wrestling physical and mental ill health, which is having a huge impact on their lives.

(Tolhurst, 2023)

Note: The device the company is looking to produce would aid with the issues mentioned above, in that people could readily have these tests at home giving them reassurance of knowing if they have the virus or not.

Prototyping

How do we avoid costly mistakes when looking at prototyping? I have given several suggestions below to be considered:

- Proof Of Concept – This is a prototype to test the idea and its functionality. It is experimental and it will involve making a test rig
 - Testing Functionality early, will save the company time and money in the long run.
- Functional Prototype – This explores the functionality of the intended final product with initial consideration of the shape,
 - Concentration spent on core requirements at this stage, designing it just good enough to not waste money on too many features.
- Appearance Prototype – This will look like the final product but does not usually function,
 - Avoid making an appearance prototype before establishing the concept function as we intend. A more cost-effective way to visualise a final version of the product.
- Final Design Prototype – This will look and function like the final product, but the component parts will most likely be made using different manufacturing method processes and materials than in mass production,
 - Make sure that considerations have been given to manufacturing processing according to the initial volume projected.
- Production Prototype – This can be used as a “Golden Sample” to show production the quality standard. The prototype appearance , function, materials and manufacturing process as the same as the final product,
 - Sorely test the prototype, as it can be a very expensive mistake if faulty goods are received.

(Design, 2023)

Product Cost

The considerations to be made when calculating the product cost should include:

➤ **The Product itself**

- Raw Material
- Masterbatch
- Sub-components bought in
- Assembly Time
- Production Time
- Allowance for Scrap
- Product Labelling
- Batteries

➤ **The Packaging**

- Will the product require a polybag
- Product Carton / Box
- Printing cost of packaging
- Inner Packaging, such as inner sleeve to house the device.
- Instructions

➤ **Storage**

- Will we store the product before its shipped?
- If so, where and how long will we store it?

➤ **Shipping**

- Pallet Wrap
- Pallet
- Pallet Labels
- Transport
- Will the pallets double stack or only single stack for floor space on trailer?
- Export Charges

Processes

There will undoubtedly be a string of uncertainties and hurdles for the company to overcome along the way with this new venture. To combat these challenges, a structured roadmap is needed to give the team a clear route to market.

- Idea generation & conceptualisation
 - The development of a new product starts with idea brainstorming and conceptualisation.
- Idea Screening
 - Following an idea generation session, the next stage would be idea screening.
 - This is the most efficient way for the company to narrow down the product ideas and likewise decide on the new covid test as such.
- Conceptual Development
 - The agreed upon idea should then be developed into a concept and tested.
 - Its important that this concept is then widely shared with the necessary departments for review.
- Outlining the business case
 - This is the point of establishing if the product can be profitable enough.
 - A business analysis will need to take place and should include, as a bare minimum,
 1. Marketing Plan
 2. Financial Forecast
- Prototyping
 - By introducing a prototype product alongside a marketing plan, the company will be able to validate the entire concept.
- The Launch

- As the company approaches the launch it needs to ensure it has considered the final pricing of the product and launch marketing plans have been followed
(Library, 2023)

Cross Reference - Prototyping

Quality & Reliability

Perspectives for consideration on how the company monitors the quality & reliability of the new device:

- Performance and intended function
- Reliability of the product within a specific time frame
- Conformity to product specifications
- Product durability and lifespan
- Product serviceability
- Physical features of the product
- Customers perception of the product

(Indeed, 2023)

Quantity

- The projected manufacturing volumes in the first year is likely to be no more than 750,000, potentially 3million per annum afterwards. (Mumby, 2023)

Safety

As mentioned in other sections, the device will adhere to a number of standards such as:

- BS EN ISO 13485 – Medical Device Quality Management Systems
- BS EN ISO 14971 – Application of Risk Management to Medical Devices

With the fact this new device will come into the medical sector, the safety of this product will also adhere to the UK Medical Device Regulations 2002. These guidelines fall under the Consumer Protection Act 1987 and ensure the medical

device will meet all the requirements, so it is acceptably safe to use and suitable for its intended purposes.

(Gov.Uk, 2023)

Cross Reference

- Standards

Shipping

Considerations to be made when reviewing the shipping of this product:

- Delivery Speed
- Delivery Range
- Tracking Capability
- Delivery Costs
- Collection / Delivery Times

(Forbes, 2023)

Social & Cultural

Following a survey carried out by the Office of National Statistics in March 2023 the following data has been established:

- Almost 1 in 5 adults -18% (Equates to 12m People) in Great Britain reported the coronavirus pandemic as an important issue facing the UK today, between 8 and 19 March 2023.
- Almost 1 in 5 adults-18%(Equates to 12m People) across Great Britain reported having used a face covering when outside their home in the past seven days during the period 22 February to 5 March 2023. For the same period, fewer than 1 in 10 adults-8% (Equates to 5.4m People) reported taking a lateral flow test in the past seven days.

- Fewer than 1 in 10 adults -8% (Equates to 5.4m People) took a lateral flow test in the last seven days (22 February to 5 March 2023). This is the same as reported for the period 25 January to 5 February 2023.
- Around 1 in 7 adults -14% (Equates to 9.4m People) avoided contact with older or other vulnerable people because of the coronavirus pandemic or other illnesses such as coughs and colds in the past seven days (22 February to 5 March 2023). This is similar to that reported for the period 21 December 2022 to 8 January 2023 -15% (Equates 10m People).

(ONS, 2023)

UK Population as of 09.08.2023 = 67,716,000

(Worldometers, 2023)

Note: The details above have been converted into the number of people, as its important for the company to understand these facts based on the sales market and needs.

Standards

Before any medical device can be sold as safe to use, it must have the marks shown below. These marks are a declaration by the manufacturer that the test meets the required standards of safety and performance.

CE MARKING

CE UKNI MARKING

UKCA MARKING

(Gov.Uk, 2023)

Under regulation 34A of the Medical Devices regulations 2002 no antigen or molecular detection COVID-19 test may be placed on the UK market without first being validated against minimum performance standards through a Coronavirus test device approval desktop review.

(Gov.Uk, 2023)

Other considerations:

BSI Conformity

- BS EN ISO 13485 – Medical Device Quality Management Systems
- BS EN ISO 14971 – Application of Risk Management to Medical Devices
- BS EN 15223-1:2021 -Symbols to be used with information to be supplied by the manufacturer (General Requirements)

(Group, 2023)

Technical Specifications

Some thoughts for discussion within the technical department:

- Results Accuracy of the test
- Response time of the test
- Is there a particular temperature the test kit should be at before performing the test.
- Storage temperature of the kit
- The measuring methods
- What will the power supply be – battery or plug – If battery, how long will they last, as in how many tests could be performed?

- Dust Protection
- What will the pass and fail indication be?

Testing

As mentioned in the standards section, The testing desktop review consists of:

- A scientific advisor reviews.
- The desktop review assurance group assesses the submission.
- The regulatory approvals committee then considers it.

Note: from 24th May 2023 applications for testing are to be submitted via Medical & Healthcare Products Regulatory Agency (MHRA).

The test report will contain the following:

- indicative performance category
- name of test
- name of manufacturer and business address
- name and business address of person who made application (if different to the manufacturer)
- date and version for instructions of use
- type of test
- date of approval
- CE certification number
- country of manufacture
- sample type

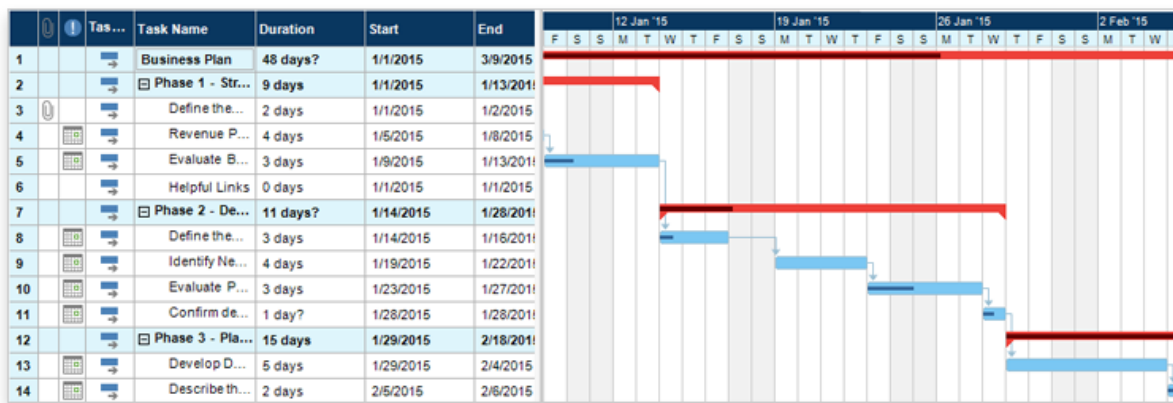
(Gov.Uk, 2023)

Cross Reference

- **Standards**

Time Scale

A Gantt chart is commonly used in project management and would accommodate this project perfectly. I have shown an example below:



The chart would allow the company to consider the following factors:

- What the various tasks are
- When each task will begin and end
- How long each task is scheduled to last
- Where activities overlap and by how much
- The start and end date of the whole project

(Gantt, 2023)

(Reference – Picture 2)

Tooling

If a decision is taken to in-house mould any of the parts intended for the new product, then new tooling will be required.

The specifications in tooling for each part would be different, however I have listed some of the areas that would need to be reviewed before ordering the tooling:

- Construction Material of the tool
- The rating of the tool - How many cycles would the tool be guaranteed for?
- What size machine will the tool be producing in?
- Will the tool require:
 - A date stamp?
 - An insert for branding?
 - A material ID stamp?
- What material will the product be produced in?
- And based on this, what will the tool wall thickness be?

- Will the tool produce 1 impression parts or more
- Will the tool produce 1 part or become a family tool

User Interface

Example instructions that can be re-designed for the new product using our current device's features



The **On/ Off** Button, which enables the device to power on and display

(Reference - Picture 3)



Simply press the **UP/ DOWN** buttons to scroll through the device's menu.

(Reference – Picture 4)

Graphics

Once turned on the illuminated display instructs the user during the virus sampling and shows the users test results.

The top right-hand corner will show a small icon which reflects the units power charge level.

Disposable Mouthpiece

NOTE: A new mouthpiece must be used for each complete new test



(Reference – Picture 5)

The disposable mouthpiece is supplied as part of the test kit and further mouthpieces can be purchased separately. (For Consideration – how many mouth pieces will be included in the first test kit provided?)

It is fitted to the device by locking its sampling port into the side of the tube. It may be attached either way, but the user **MUST** place the lipped end into mouth area until through the wide bore, lipped end, shown on the picture above.

Power Unit

The power unit is located in the rear of the device. It holds 2 x AA alkaline batteries; these should provide at least one thousand tests (to be confirmed by technical / quality department before confirmed)

NOTE: Do not use rechargeable AA Batteries these have a lower power capacity than Alkaline.

EXAMPLE INSTRUCTIONS TO CARRY OUT THE TEST:

- | | |
|---------------|---|
| STEP 1 | Turn on the Device |
| STEP 2 | Wait until the device beeps once and the screen powers on |
| STEP 3 | The device will become ready to take the test |
| STEP 4 | User is advised to take a deep breath to provide the test |
| STEP 5 | When providing a sample, the user is guided to blow constant, with a steady flow of air, similar to a whistling action. Blowing too softly could invalidate the test. |
| STEP 6 | The user must continue to blow until the operator confirms the test is complete. |
| STEP 7 | The test will now be analysed with the devices controlling electronics and software-based systems. |
| STEP 8 | The result will be shown on the screen as a PASS or FAIL |
| STEP 9 | Remove the mouthpiece and power down the device. |

(Laboratories, 2023)

FINAL CONSIDERATION'S

- Further research should be carried out if the initial product launch will include international sales.
- It may also be worth noting that during my research I established some studies have already been carried out in this area using a breathalyser machine.
 - Researchers have developed a unique method of detecting Covid in breath samples using RNA detection.
 - The study was carried out that determined that Covid can be readily detected in the breath and is more predictive of lower respiratory tract (Forum, 2021)

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[on](https://innovate-design.co.uk/prototyping-process/?msclkid=298b0be7e1d0101f997e6f3476ea526a&utm_source=bing&utm_medium=cpc&utm_campaign=Prototype&utm_term=prototype%20production&utm_content=Prototype%20producti)

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[people](https://www.pragmaticinstitute.com/resources/articles/product/goals-readiness-and-constraints-the-three-dimensions-of-product-launch/#:~:text=There%20are%20many%20possible%20launch,time%2C%20money%2C%20and%20people).

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Pictures / Diagrams

Picture 1 - Free Customer Persona & Profile Templates | Smartsheet

Picture 2 - <https://www.gantt.com>

Pictures 3-5 - <https://www.lionlaboratories.com>