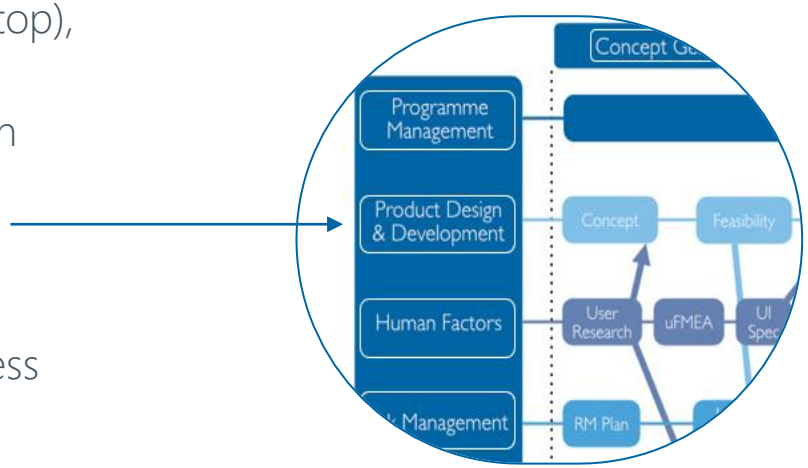
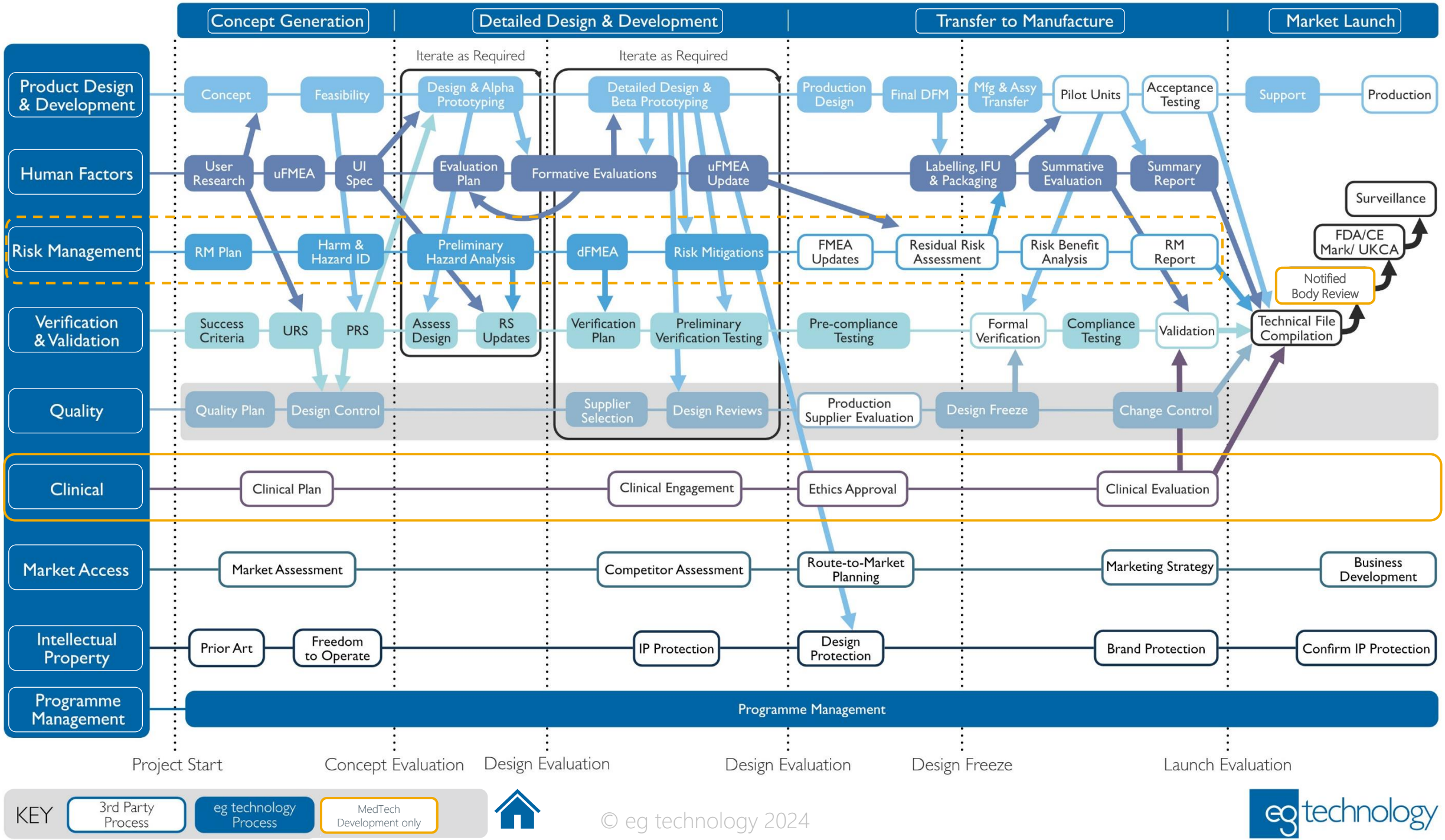
Product Design & Development Plan – Interactive Guide

How to Use This Document

- The diagram on the following pages shows the key stages (along the top), and key processes (down the left-hand side) involved with a typical product design project. Any MedTech specific steps/streams have been highlighted in yellow.
- The arrows represent the interactions between the various processes
- Click on the **white heading boxes** to find out more about each process
- Press  at the bottom of the page to return to the full process diagram
- Diagram Key
  - Colour fill boxes: services offered by 'eg technology'
  - White boxes: services to be provided externally – eg can recommend 3rd parties if requested
  - Outlined yellow boxes – MedTech specific programme requirements

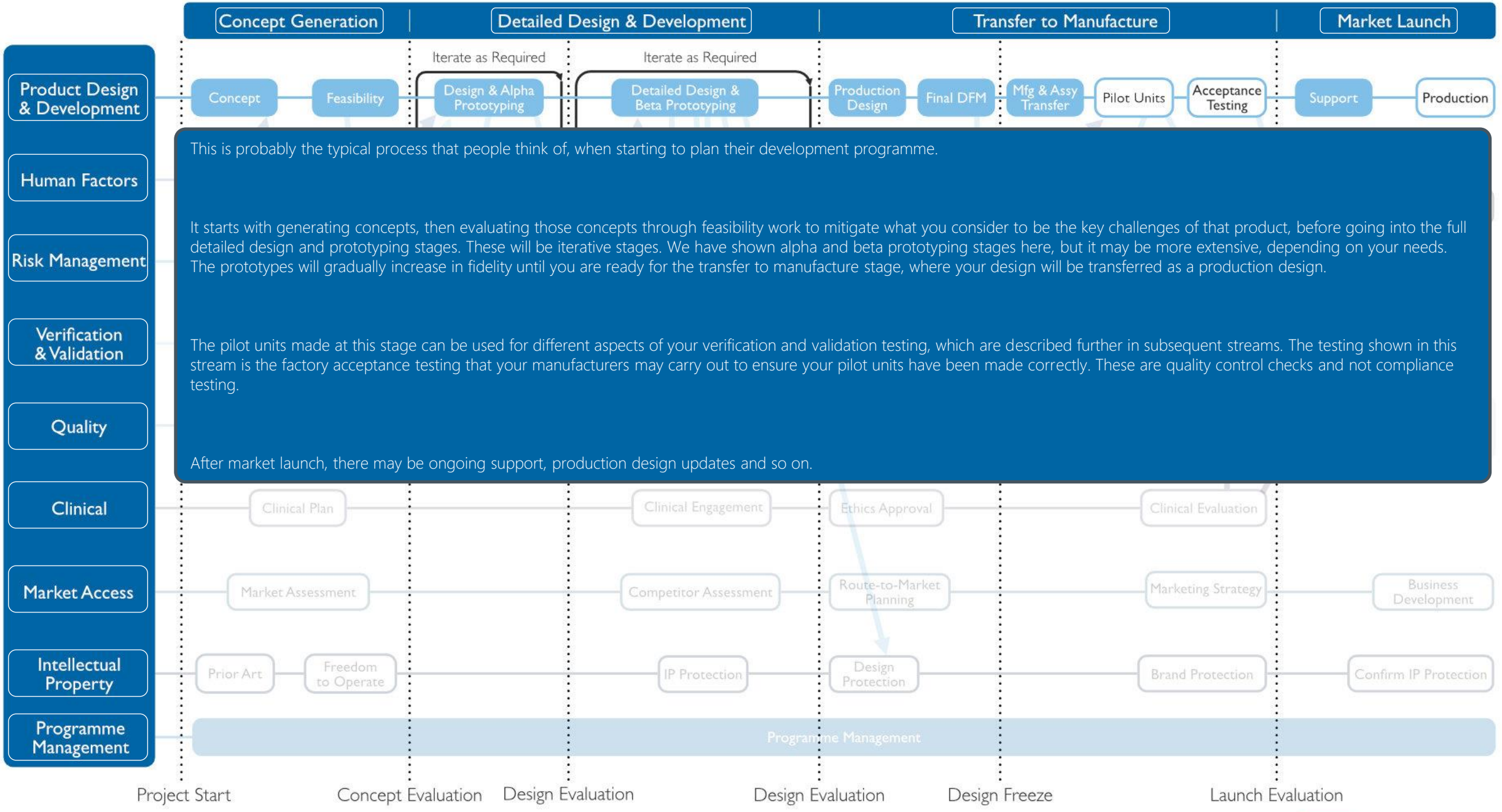


Please note this document is intended to be used as a framework only, and each project should be individually tailored and adapted.



KEY: 3rd Party Process | eg technology Process | MedTech Development only

eg technology



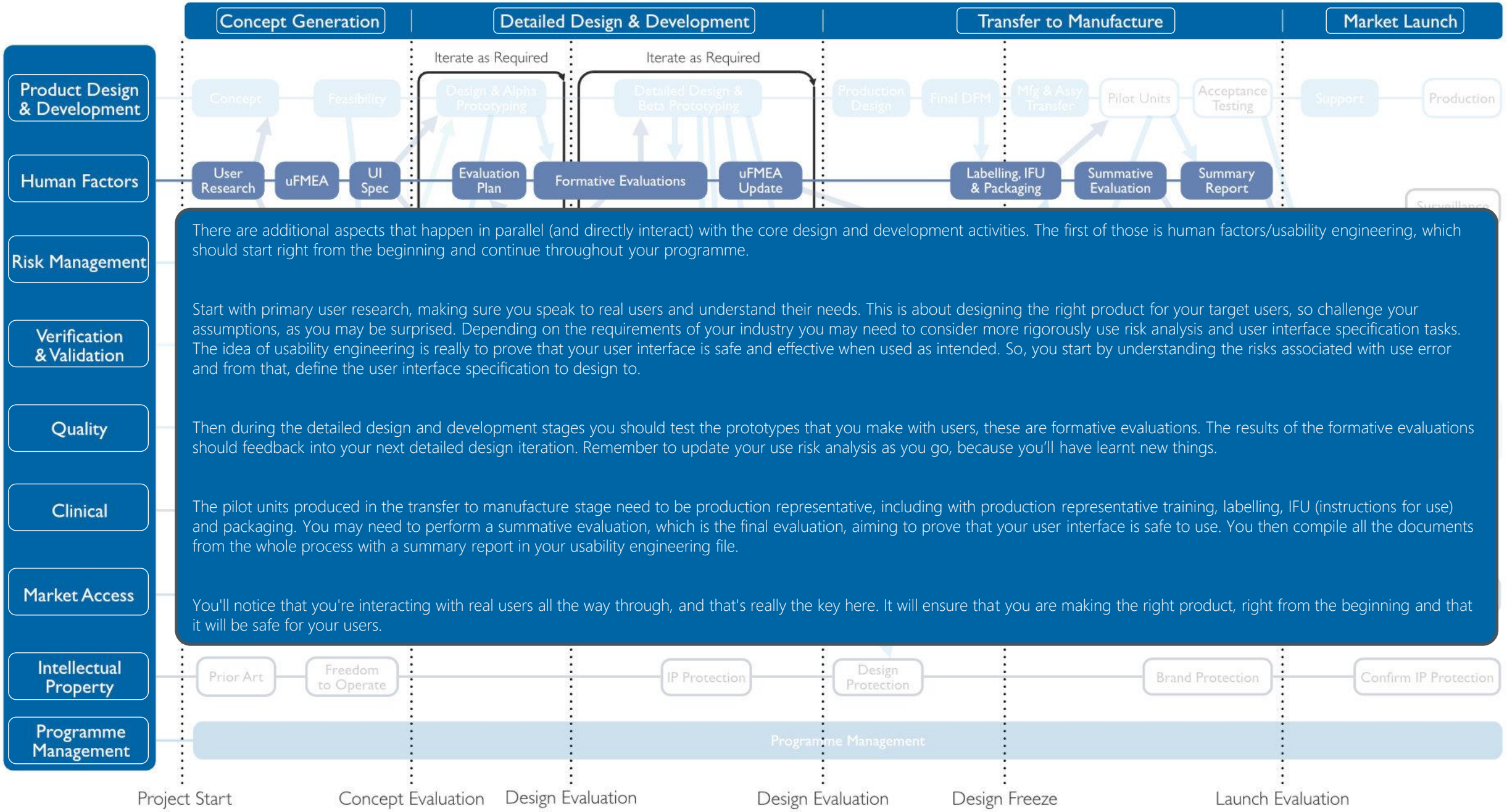
This is probably the typical process that people think of, when starting to plan their development programme.

It starts with generating concepts, then evaluating those concepts through feasibility work to mitigate what you consider to be the key challenges of that product, before going into the full detailed design and prototyping stages. These will be iterative stages. We have shown alpha and beta prototyping stages here, but it may be more extensive, depending on your needs. The prototypes will gradually increase in fidelity until you are ready for the transfer to manufacture stage, where your design will be transferred as a production design.

The pilot units made at this stage can be used for different aspects of your verification and validation testing, which are described further in subsequent streams. The testing shown in this stream is the factory acceptance testing that your manufacturers may carry out to ensure your pilot units have been made correctly. These are quality control checks and not compliance testing.

After market launch, there may be ongoing support, production design updates and so on.

KEY: 3rd Party Process | eg technology Process | MedTech Development only



There are additional aspects that happen in parallel (and directly interact) with the core design and development activities. The first of those is human factors/usability engineering, which should start right from the beginning and continue throughout your programme.

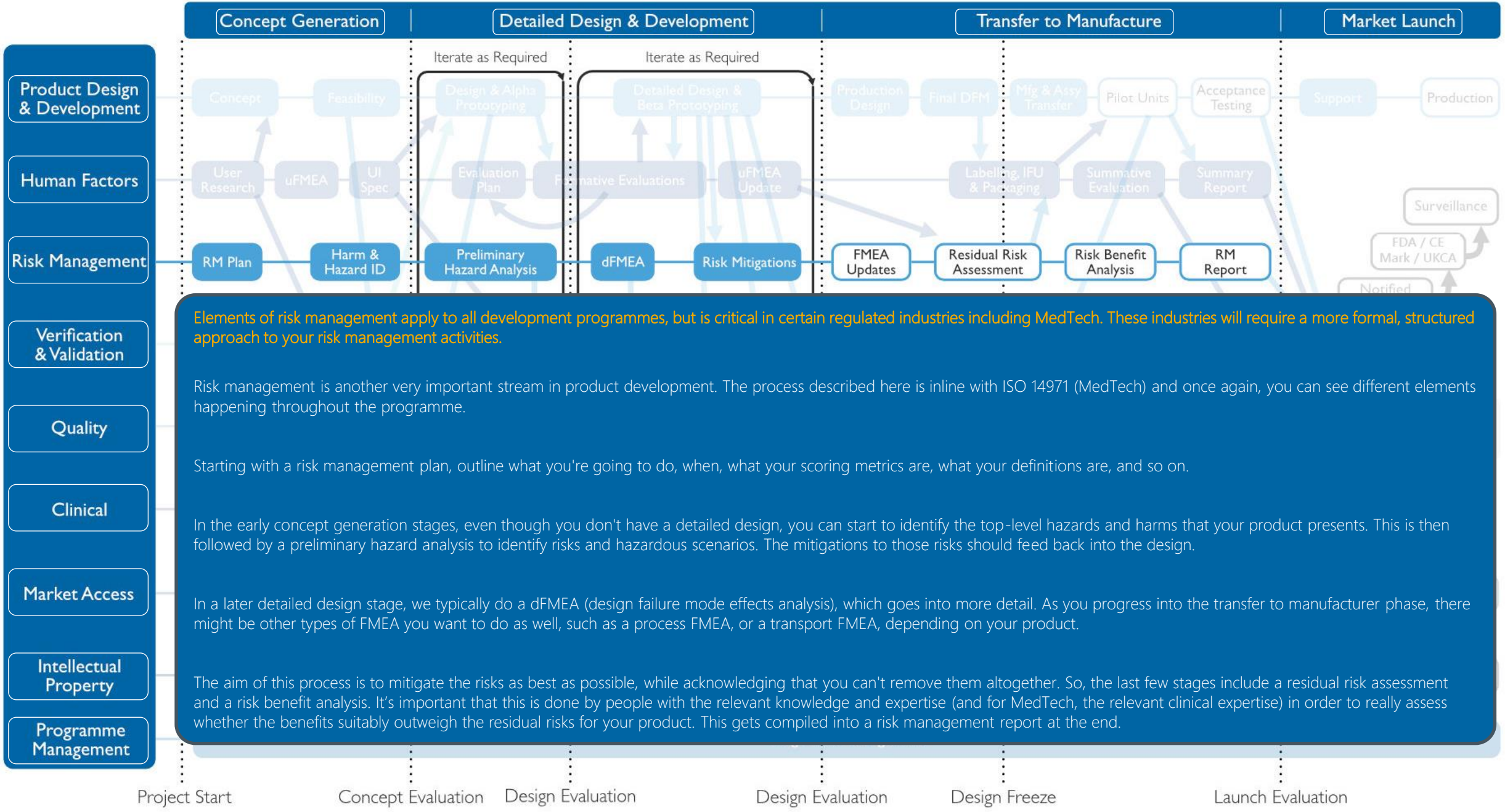
Start with primary user research, making sure you speak to real users and understand their needs. This is about designing the right product for your target users, so challenge your assumptions, as you may be surprised. Depending on the requirements of your industry you may need to consider more rigorously use risk analysis and user interface specification tasks. The idea of usability engineering is really to prove that your user interface is safe and effective when used as intended. So, you start by understanding the risks associated with use error and from that, define the user interface specification to design to.

Then during the detailed design and development stages you should test the prototypes that you make with users, these are formative evaluations. The results of the formative evaluations should feedback into your next detailed design iteration. Remember to update your use risk analysis as you go, because you'll have learnt new things.

The pilot units produced in the transfer to manufacture stage need to be production representative, including with production representative training, labelling, IFU (instructions for use) and packaging. You may need to perform a summative evaluation, which is the final evaluation, aiming to prove that your user interface is safe to use. You then compile all the documents from the whole process with a summary report in your usability engineering file.

You'll notice that you're interacting with real users all the way through, and that's really the key here. It will ensure that you are making the right product, right from the beginning and that it will be safe for your users.

KEY 3rd Party Process | eg technology Process | MedTech Development only



Elements of risk management apply to all development programmes, but is critical in certain regulated industries including MedTech. These industries will require a more formal, structured approach to your risk management activities.

Risk management is another very important stream in product development. The process described here is inline with ISO 14971 (MedTech) and once again, you can see different elements happening throughout the programme.

Starting with a risk management plan, outline what you're going to do, when, what your scoring metrics are, what your definitions are, and so on.

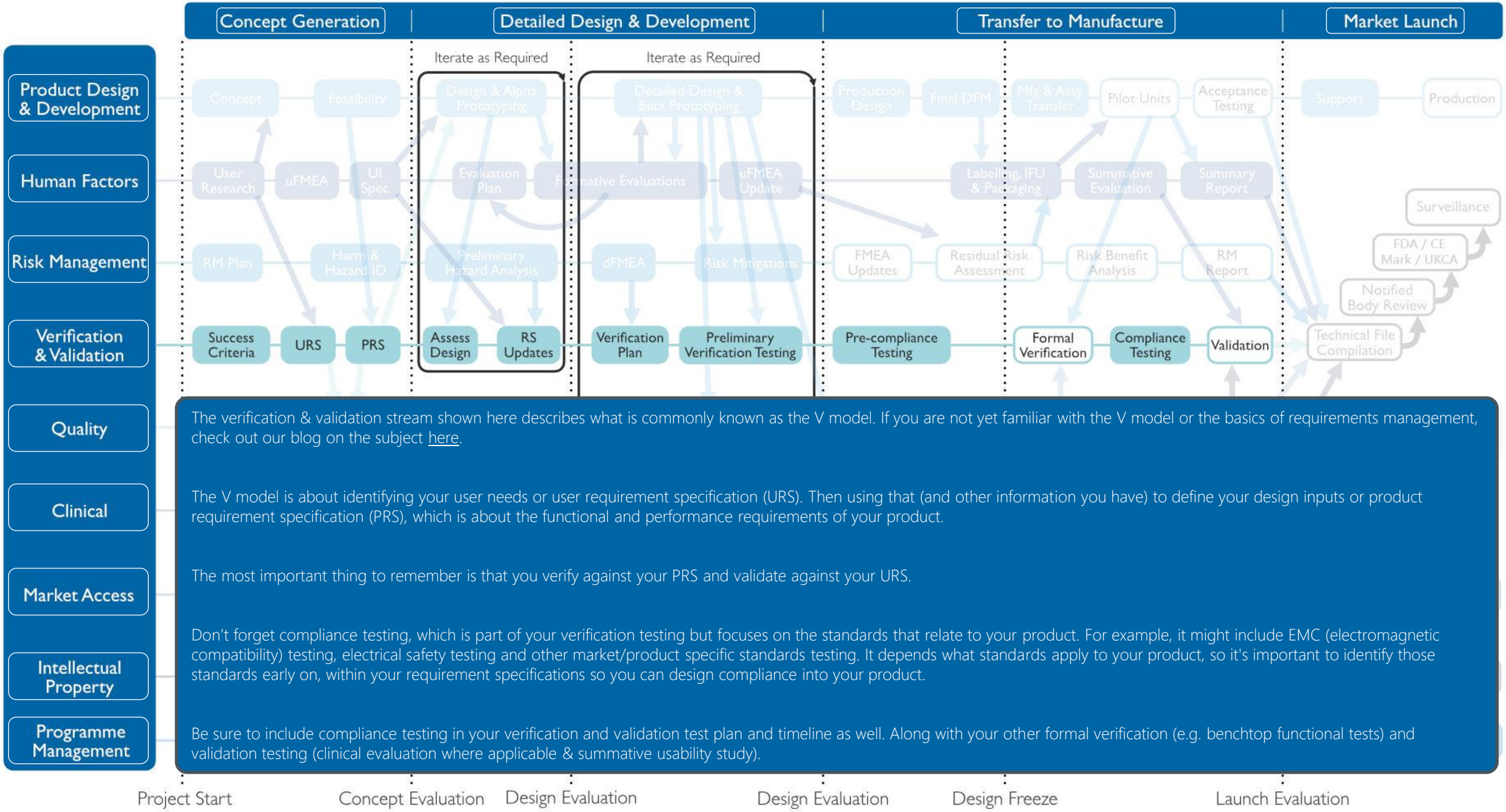
In the early concept generation stages, even though you don't have a detailed design, you can start to identify the top-level hazards and harms that your product presents. This is then followed by a preliminary hazard analysis to identify risks and hazardous scenarios. The mitigations to those risks should feed back into the design.

In a later detailed design stage, we typically do a dFMEA (design failure mode effects analysis), which goes into more detail. As you progress into the transfer to manufacturer phase, there might be other types of FMEA you want to do as well, such as a process FMEA, or a transport FMEA, depending on your product.

The aim of this process is to mitigate the risks as best as possible, while acknowledging that you can't remove them altogether. So, the last few stages include a residual risk assessment and a risk benefit analysis. It's important that this is done by people with the relevant knowledge and expertise (and for MedTech, the relevant clinical expertise) in order to really assess whether the benefits suitably outweigh the residual risks for your product. This gets compiled into a risk management report at the end.

KEY: 3rd Party Process | eg technology Process | MedTech Development only

eg technology



The verification & validation stream shown here describes what is commonly known as the V model. If you are not yet familiar with the V model or the basics of requirements management, check out our blog on the subject here.

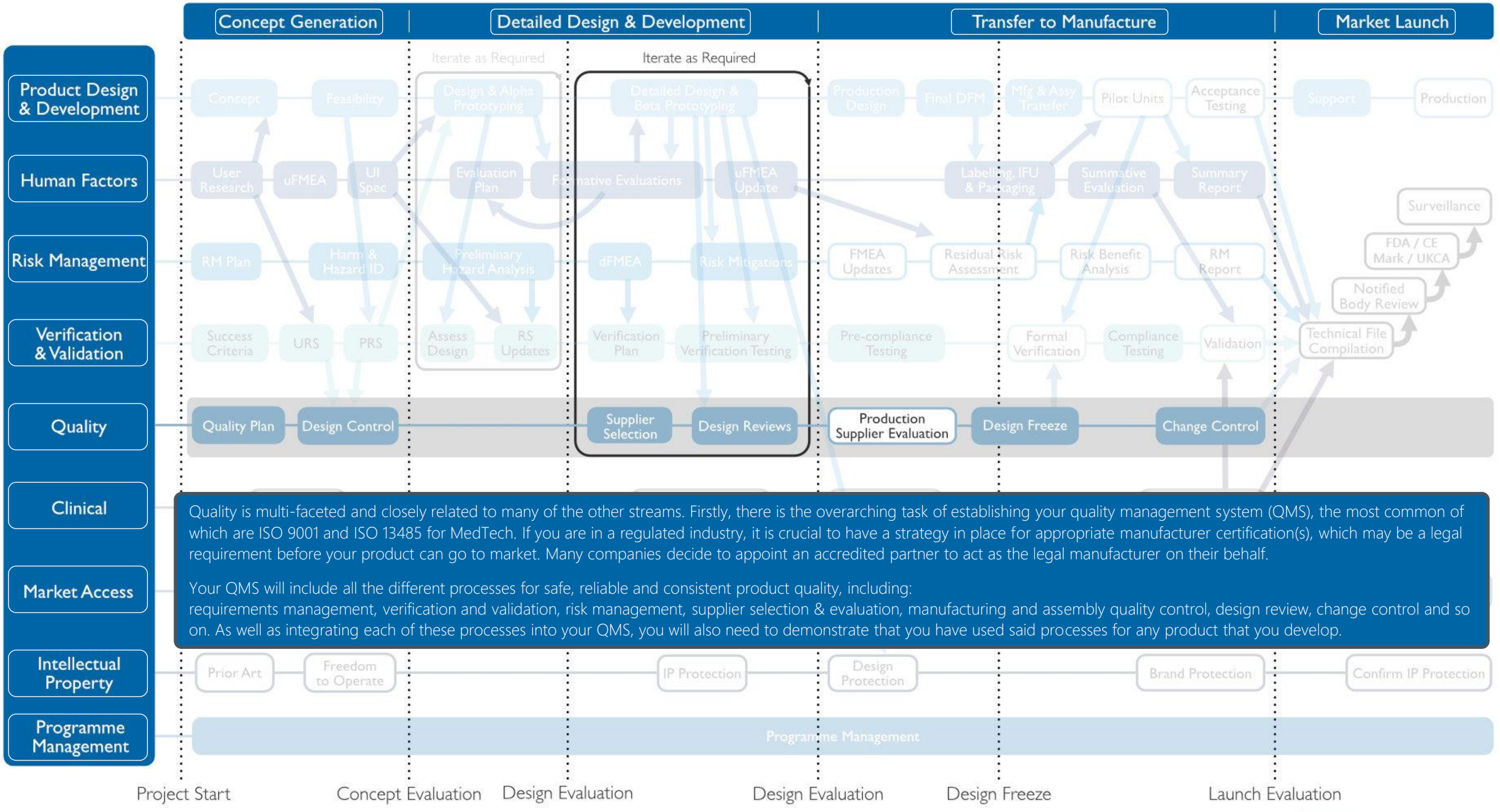
The V model is about identifying your user needs or user requirement specification (URS). Then using that (and other information you have) to define your design inputs or product requirement specification (PRS), which is about the functional and performance requirements of your product.

The most important thing to remember is that you verify against your PRS and validate against your URS.

Don't forget compliance testing, which is part of your verification testing but focuses on the standards that relate to your product. For example, it might include EMC (electromagnetic compatibility) testing, electrical safety testing and other market/product specific standards testing. It depends what standards apply to your product, so it's important to identify those standards early on, within your requirement specifications so you can design compliance into your product.

Be sure to include compliance testing in your verification and validation test plan and timeline as well. Along with your other formal verification (e.g. benchtop functional tests) and validation testing (clinical evaluation where applicable & summative usability study).

KEY: 3rd Party Process | eg technology Process | MedTech Development only

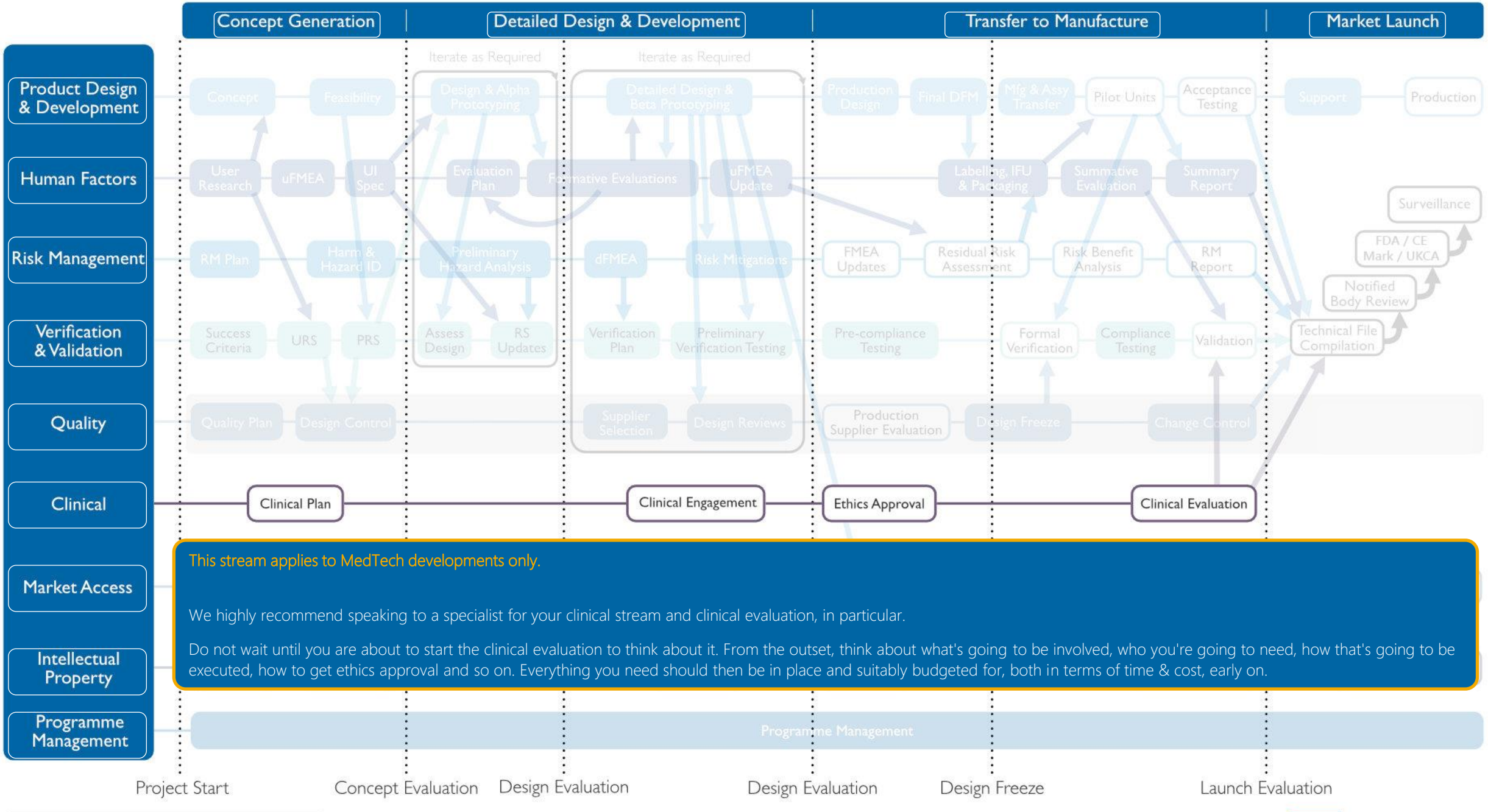


Quality is multi-faceted and closely related to many of the other streams. Firstly, there is the overarching task of establishing your quality management system (QMS), the most common of which are ISO 9001 and ISO 13485 for MedTech. If you are in a regulated industry, it is crucial to have a strategy in place for appropriate manufacturer certification(s), which may be a legal requirement before your product can go to market. Many companies decide to appoint an accredited partner to act as the legal manufacturer on their behalf.

Your QMS will include all the different processes for safe, reliable and consistent product quality, including:
requirements management, verification and validation, risk management, supplier selection & evaluation, manufacturing and assembly quality control, design review, change control and so on. As well as integrating each of these processes into your QMS, you will also need to demonstrate that you have used said processes for any product that you develop.

KEY: 3rd Party Process | eg technology Process | MedTech Development only

eg technology

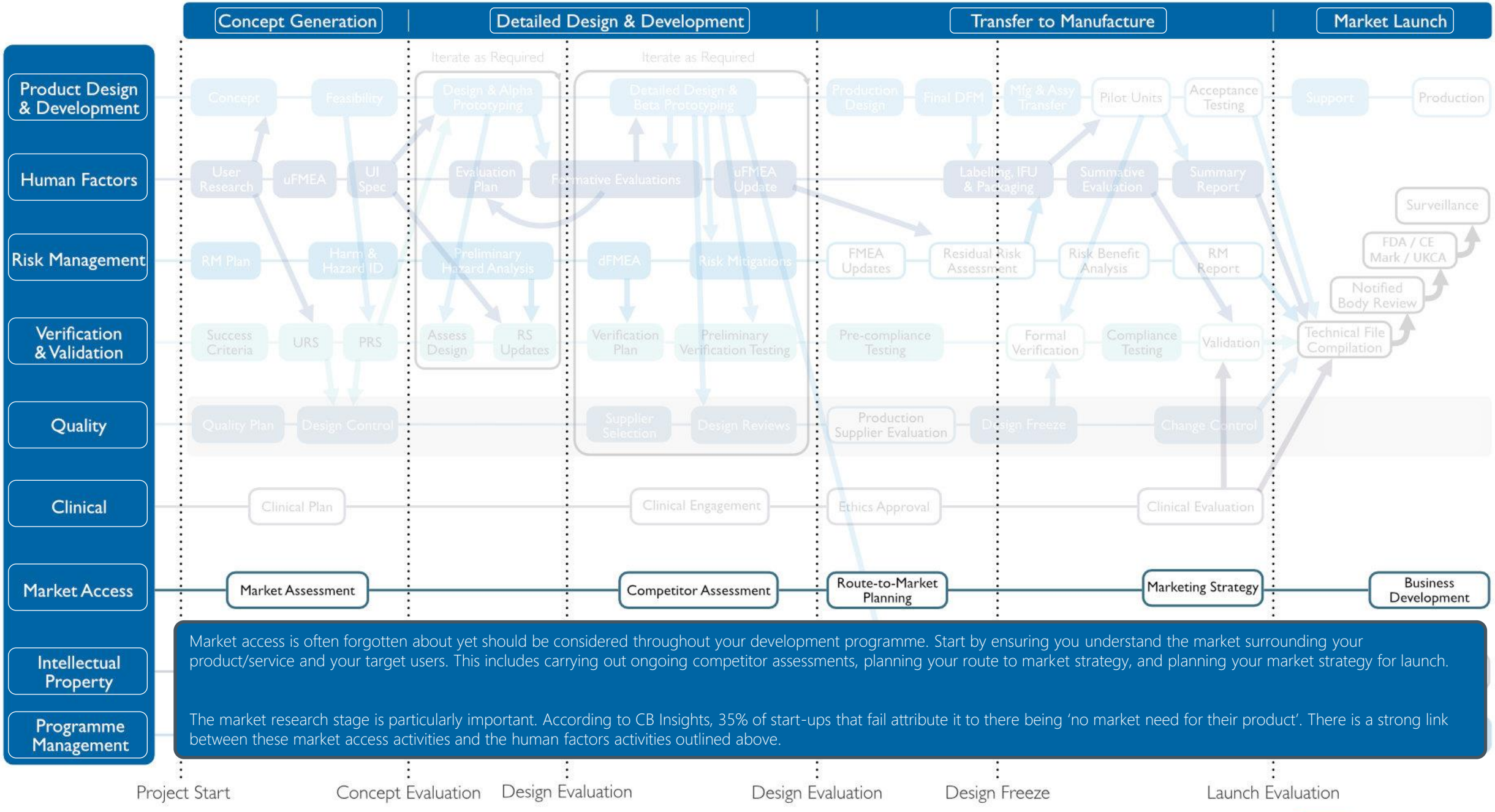


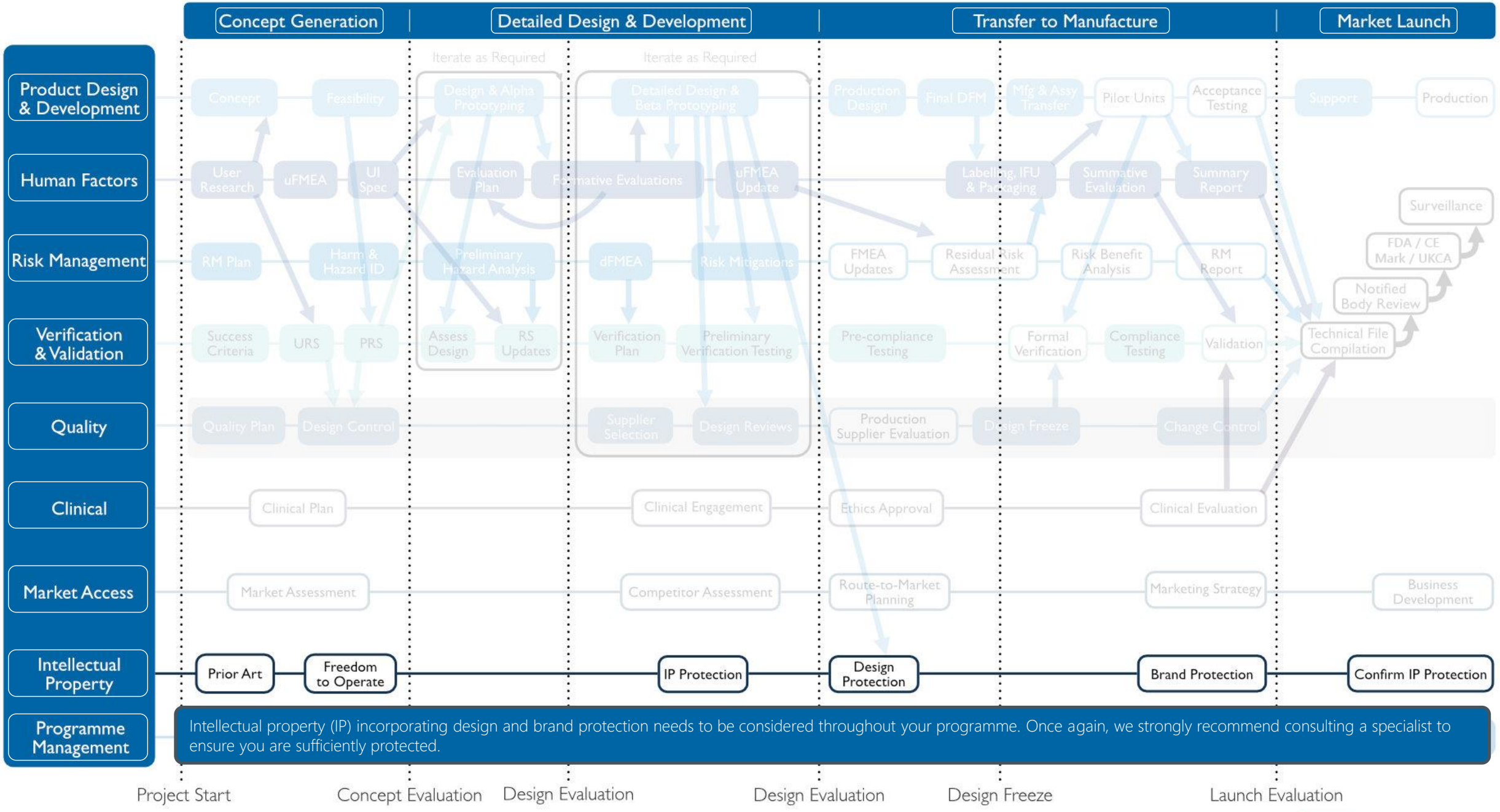
This stream applies to MedTech developments only.

We highly recommend speaking to a specialist for your clinical stream and clinical evaluation, in particular.

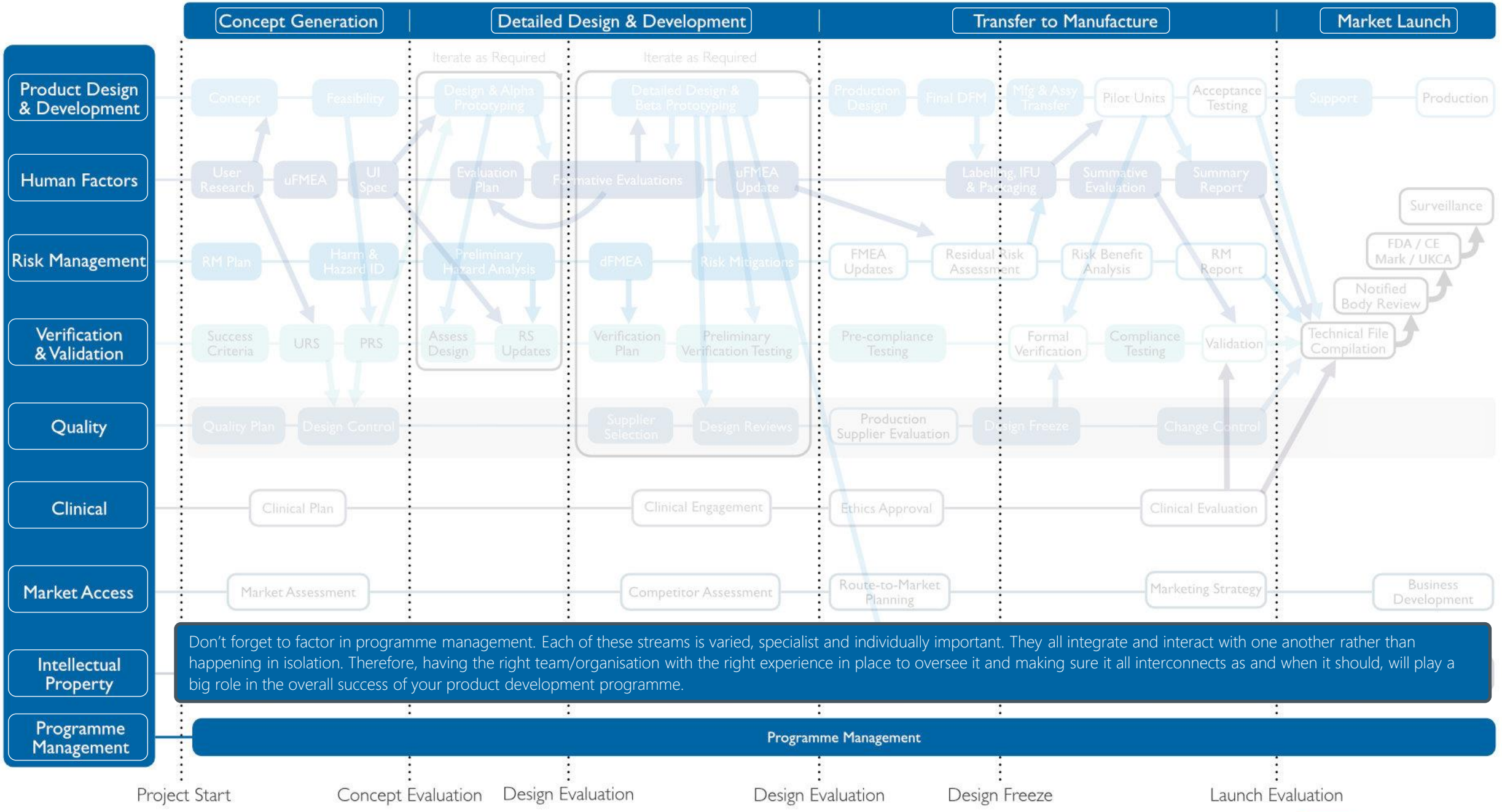
Do not wait until you are about to start the clinical evaluation to think about it. From the outset, think about what's going to be involved, who you're going to need, how that's going to be executed, how to get ethics approval and so on. Everything you need should then be in place and suitably budgeted for, both in terms of time & cost, early on.

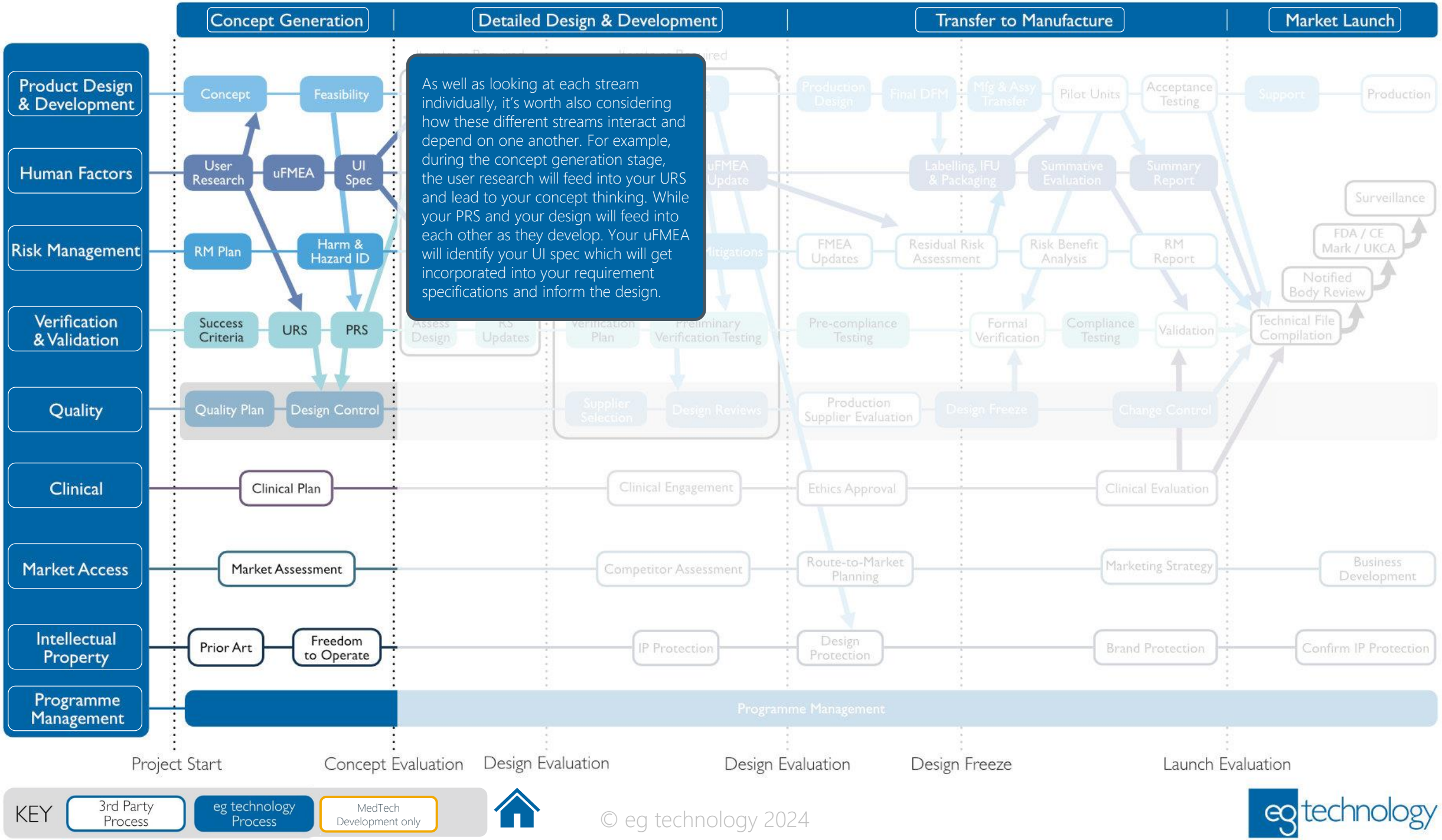
KEY: 3rd Party Process | eg technology Process | MedTech Development only

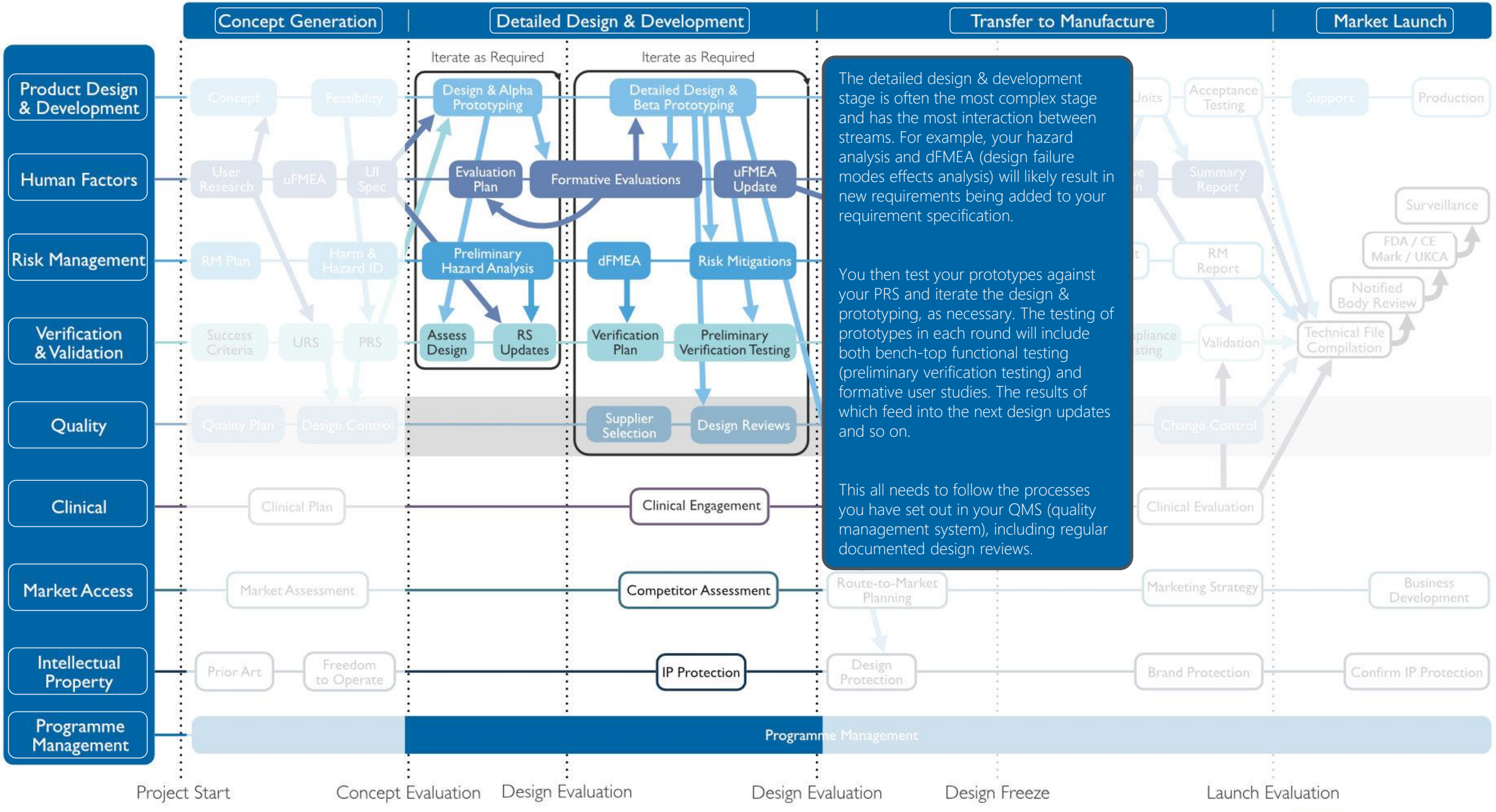




KEY: 3rd Party Process | eg technology Process | MedTech Development only







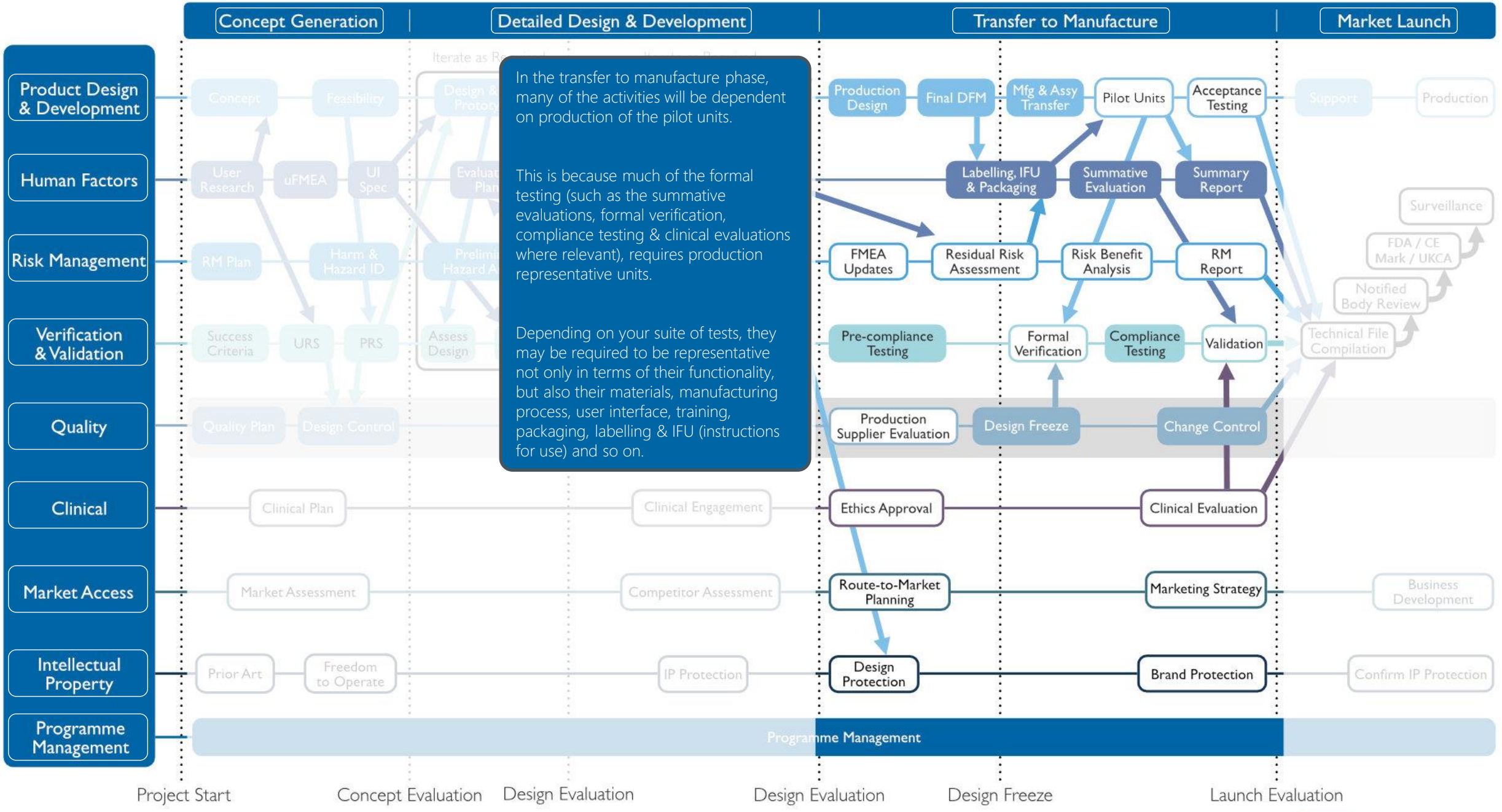
The detailed design & development stage is often the most complex stage and has the most interaction between streams. For example, your hazard analysis and dFMEA (design failure modes effects analysis) will likely result in new requirements being added to your requirement specification.

You then test your prototypes against your PRS and iterate the design & prototyping, as necessary. The testing of prototypes in each round will include both bench-top functional testing (preliminary verification testing) and formative user studies. The results of which feed into the next design updates and so on.

This all needs to follow the processes you have set out in your QMS (quality management system), including regular documented design reviews.

KEY: 3rd Party Process | eg technology Process | MedTech Development only

eg technology



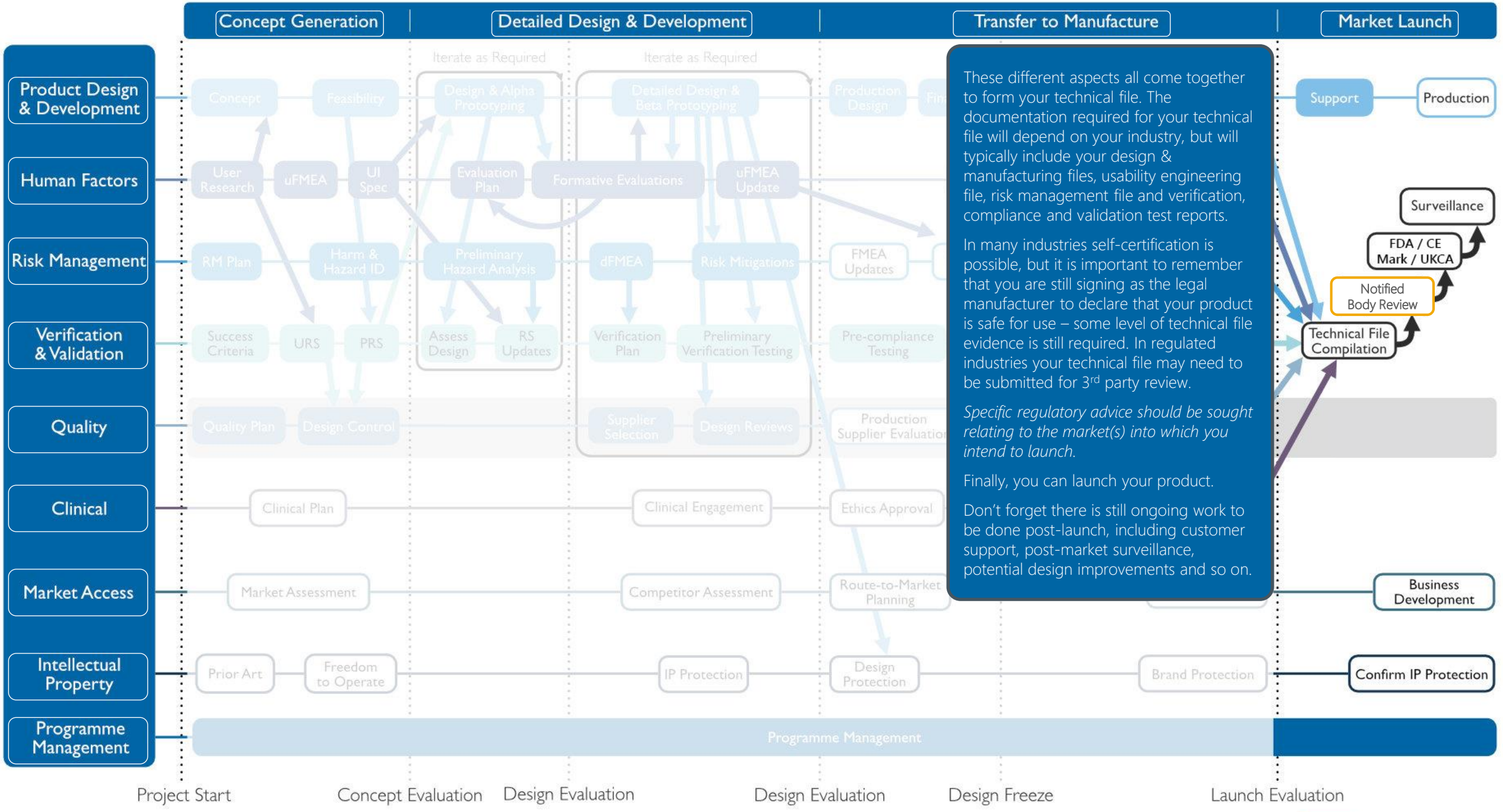
KEY

3rd Party Process

eg technology Process

MedTech Development only

eg technology



These different aspects all come together to form your technical file. The documentation required for your technical file will depend on your industry, but will typically include your design & manufacturing files, usability engineering file, risk management file and verification, compliance and validation test reports.

In many industries self-certification is possible, but it is important to remember that you are still signing as the legal manufacturer to declare that your product is safe for use – some level of technical file evidence is still required. In regulated industries your technical file may need to be submitted for 3rd party review.

Specific regulatory advice should be sought relating to the market(s) into which you intend to launch.

Finally, you can launch your product.

Don't forget there is still ongoing work to be done post-launch, including customer support, post-market surveillance, potential design improvements and so on.

KEY: 3rd Party Process | eg technology Process | MedTech Development only

eg technology

To discuss your product design and development requirements, please get in touch with our team:

+44 (0) 1223 813184

design@egtechnology.co.uk

www.egtechnology.co.uk