

## How Healthy is your Project?

Regular review and reflection by the Project Team is essential to ensure a Project is meeting its overall objectives. This should be performed at significant milestones and decision points in the Project's life, and it should not be assumed that apparently 'obvious' items such as Sponsorship, Budget, Commercial value, etc. have remained unchanged - especially during times of organisational transition.

The set of general questions in the Index leads to more detailed diagnostic questions. There are no 'correct' answers - rather, the Team can discuss each point as required and, if a satisfactory response is elicited, then the Project should be in good order.

The tool can be facilitated by the Project Leader, and is best done in an open, supportive meeting where Team Members are encouraged to express their views.

**Pharmaceutical Industry Project Management Group**

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Health Check 1	Prompts	Commentary	Symptoms of failure
<p><b>Who wants this Project and is there a justifiable business case?</b></p> <p><i>Sponsors and Scope - How has the legitimacy of the Project been established and what work should fall within the remit of the Project?</i></p>	<ul style="list-style-type: none"> <li>• Are senior Leaders aware of the Project?</li> <li>• Have senior management sponsors taken ownership of the Project?</li> <li>• Are the people affected by the Project (stakeholders) aware it has been established?</li> <li>• Have the sponsors encouraged all stakeholders to identify and confirm their commitment to the Project?</li> <li>• Do all concerned understand the overall scope of the Project?</li> <li>• Is there a clear management procedure for agreeing changes to scope?</li> </ul>	<ul style="list-style-type: none"> <li>• Sponsors must be identified at an appropriate level of seniority in the organisation to own and give credence at a strategic level to: <ul style="list-style-type: none"> <li>○ The Product Profile</li> <li>○ The Business Case</li> <li>○ The Project Plan</li> </ul> </li> <li>• Sponsors must promote the Project not just within, for instance Research &amp; Development, but also elsewhere in the organisation such as Corporate Headquarters, Manufacturing &amp; Supply, and the Commercial business both at home and overseas.</li> <li>• Projects need to have clear Scope, and uncontrolled diversion into unauthorised areas must be strenuously avoided.</li> </ul>	<ul style="list-style-type: none"> <li>• No ownership of the Project.</li> <li>• No coherent voice from senior management.</li> <li>• Conflicting requirements placed upon the Project.</li> <li>• Uncontrolled changes to Scope lead to uncontrolled demands on time, human resource and budget, imperilling commercial success.</li> </ul>
<p><i>Product Profile - Has due consideration been given to scientific and commercial requirements in equal measure?</i></p>	<ul style="list-style-type: none"> <li>• Have the scientific and commercial elements of the Product Profile been established and agreed by a broad section of the organisation from Sponsors to Project Team experts?</li> <li>• Does the Project Team regularly check emergent information against the expectations of the Product Profile?</li> <li>• Have minimum quantified requirements been set in the Profile, below which the Project will be considered non-viable?</li> </ul>	<ul style="list-style-type: none"> <li>• The Product Profile defines the Product in terms of functionality, quantity and quality and embraces both scientific and commercial elements.</li> <li>• It must be defined, agreed, managed and controlled in order to maximise the value and minimise the risk of the endeavour.</li> <li>• The Project Plan then links the needs defined by the Product Profile to the specific tasks to be undertaken by the Project Team</li> </ul>	<ul style="list-style-type: none"> <li>• Not possible to put together a coherent Project plan and assign responsibilities to expert staff to accomplish the work required.</li> <li>• Not clear whether Proof of Concept has been achieved prior to full development.</li> <li>• Not sure whether the Product is likely to be a commercial success.</li> </ul>

Health Check 1 (contd.)	Prompts	Commentary	Symptoms of failure
<p><i>Commercialisation - What thinking can be embedded in early stage development to help underpin eventual commercial success?</i></p>	<ul style="list-style-type: none"> <li>• Is the development candidate robust and developable and capable of being fashioned into a medicine?</li> <li>• Is the situation with regard to Intellectual Property in its broadest sense sufficiently favourable to underpin successful Lifecycle management?</li> <li>• Have the criteria for transition into full development at Proof of Concept been set so as to establish a likelihood of commercial success?</li> <li>• Does the clinical programme encompass health outcome research from an early stage to support optimum pricing and reimbursement?</li> <li>• Have ways to maximise revenues during the various stages of the product lifecycle been considered during development?</li> </ul>	<ul style="list-style-type: none"> <li>• It is not sufficient to make first registration an end in itself. The needs of the customers (patients, prescribers and payers - and shareholders) must be established at the earliest stage of the Project so that the market is optimised at launch to maximise its value to the Company and to its customers.</li> <li>• In considering the Lifecycle management of the new product, it is necessary to gain rapid access to the major markets, secure the most favourable climate for pricing and reimbursement, and finally to minimise the effects of patent expiry on the mature product.</li> </ul>	<ul style="list-style-type: none"> <li>• Failure to embed commercial requirements into early stage development will damage the overall value of the Product</li> </ul>
<p><i>Commercial Value and Portfolio Priority - What needs to be established to indicate future commercial success?</i></p>	<ul style="list-style-type: none"> <li>• Have the value of the Project and the likely commercial return on investment been calculated?</li> <li>• Has the impact of alternative development strategies ('buy up/buy down') been quantified?</li> <li>• Has the value been adjusted according to the inherent risk in the Project?</li> <li>• What is the position of the Project within the organisation's overall Portfolio of Projects and what is its priority?</li> <li>• What level of investment is required to ensure rapid commercial return yet optimise lifecycle management?</li> </ul>	<ul style="list-style-type: none"> <li>• The Business Case is a financial summary drawn from the Strategic Plan and must align the Project objectives with Corporate objectives.</li> <li>• The Business Case should be updated with new information (both internal and external e.g. competitor status) in order to reconfirm at regular intervals that the Project should continue</li> </ul>	<ul style="list-style-type: none"> <li>• No internal comprehension of why the Project exists.</li> <li>• No drive to take it forward.</li> </ul>

Health Check 2	Prompts	Commentary	Symptoms of failure
<p><b>Is there a Project Leader and is there a Team?</b></p> <p><i>Is there a Project Leader and what management style would you wish them to adopt?</i></p>	<ul style="list-style-type: none"> <li>• Is there a Project Leader? <i>And does the Project Leader -</i></li> <li>• Build Project legitimacy by establishing Purpose?</li> <li>• Build co-operative relationships between all the People involved, including Sponsors, Stakeholders and Project Team members (internal and external)?</li> <li>• Encourage communicative links and manage the interfaces within and between the internal and external organisations?</li> <li>• Establish who is Responsible for Project work, who is Accountable for ensuring its completion, who needs to be Consulted, and who needs to be Informed?</li> <li>• Set expectations of Team members - but leave experts to manage themselves?</li> <li>• Encourage the Team members to actively critique their objectives, plan thoroughly and review their own progress?</li> <li>• Take decisions based on the likely future impact?</li> <li>• Identify risks and address them?</li> <li>• Base plans around evidence collection, not just task completion?</li> <li>• Develop a resource acquisition strategy?</li> <li>• Use feedback to manage future direction?</li> </ul>	<ul style="list-style-type: none"> <li>• A Project Leader appropriate in experience and stature to the needs of the Project should be appointed.</li> <li>• The Project Leader is responsible for Project Communications with Sponsors, External stakeholders and Functional groups.</li> </ul>	<ul style="list-style-type: none"> <li>• No balance between the demands of the Project and the capabilities of the expert functions.</li> <li>• No shared vision of the product being developed.</li> <li>• No common understanding of the development process being followed.</li> <li>• No central focus for all participants, both internal and external to the company.</li> </ul>

Health Check 2 (contd.)	Prompts	Commentary	Symptoms of failure
<p><i>The Team - Who should be involved and what kind of Team structure works best?</i></p>	<ul style="list-style-type: none"> <li>• Is all the required expertise available to the core Team (strategic) and the associated Subteams (operational)?</li> <li>• Is the expertise available internally, or from external partners/contractors, or both, and how is the mix managed?</li> <li>• Are the Team members aware of their responsibilities and capable of delivering their functional tasks?</li> <li>• Are the Subteams tasks well managed and communicated?</li> <li>• Are Project Team members empowered to represent their functional expertise?</li> <li>• Are there clear procedures for measuring performance of Team members?</li> <li>• Is there a culture of Learning and Development in the Project Team and the organisation at large as the needs of the Project unfold?</li> </ul>	<ul style="list-style-type: none"> <li>• Ideally, the Project Leader will appoint (or agree with functional management) a core Team of representatives from the key functional areas (either internal or external resource).</li> <li>• Between them, they will be responsible for ensuring that all Project tasks are correctly identified and managed through a series of Subteams.</li> </ul>	<ul style="list-style-type: none"> <li>• The Project Leader will run into great difficulty unless in possession of a management style and a Team structure that is able to embrace varying seniority, experience and personality within Project Team members, both from within the organisation and from external partners/contractors, and Project Teams that are spread across barriers of time, geography and culture.</li> </ul>

Health Check 3	Prompts	Commentary	Symptoms of failure
<p><b>Is there a Project Plan and Budget?</b></p> <p><i>Plan - Does it satisfy strategic and operational needs and what is the end point?</i></p>	<ul style="list-style-type: none"> <li>• Are the plans laid out to the agreed end point?</li> <li>• Is the level of detail appropriate to the planning horizon?</li> <li>• Do plans distinguish between strategic, operational and functional requirements?</li> <li>• Are the plans laid out to remove uncertainty as rapidly and as cheaply as possible?</li> <li>• Do the plans have the flexibility to cope with the unexpected?</li> <li>• Did the planning process include all those needed to make a commitment, and do they understand what that commitment is?</li> </ul>	<ul style="list-style-type: none"> <li>• A Project Plan must be laid out to completion, identifying the tasks and their interdependencies. The Plan defines the critical path and major milestones. It also helps define the decision point at which uncertainty of outcome can be further reduced by the discharge of risk based on emergent data.</li> </ul>	<ul style="list-style-type: none"> <li>• Without a Plan there is no outward and visible sign that the Project Team and the organisation understand what needs to be done.</li> <li>• Without a Plan, there is anarchy and confusion and the Project will fail through time overrun, cost overrun or failure to meet specification - and usually all three.</li> </ul>
<p><i>Budget - How will funding be planned to ensure Project continuity?</i></p>	<ul style="list-style-type: none"> <li>• Is the organisation ready and prepared to fund to a specific go/no go decision, or to completion?</li> <li>• Have all Project costs, direct and indirect, internal and external, been identified to the required level of detail for the budget cycle now and in the future?</li> <li>• Who holds the budget? Project Leader or Functional Leader?</li> <li>• Do the financial systems unambiguously map Project spend to Functional spend and vice versa?</li> </ul>	<ul style="list-style-type: none"> <li>• Level of investment will depend on the agreed Business Case. It will encompass internal costs of staff (how many, when required, and the daily/annual rate for each functional area), external costs (chemical intermediates, contract toxicology, clinical trials investigator payments etc) and internal cross-charge costs for services from other parts of the business such as Manufacturing, Marketing etc.</li> <li>• Where the Project is not a cost centre, the budget should map unambiguously to a defined budget within the functional areas.</li> <li>• Where infrastructure works are required (buildings, plant etc) the appropriate capital expenditure budgets must be drawn up and approved.</li> </ul>	<ul style="list-style-type: none"> <li>• Failure to gain commitment to the required Project spend can cause severe delay at critical stages of the work whilst alternative sources of funding are sought.</li> </ul>

Health Check 4	Prompts	Commentary	Symptoms of failure
<p><b>Does the Project want to Make or Buy?</b></p> <p><i>Is the required expertise available in-house, or only available from partners or contractors?</i></p>	<ul style="list-style-type: none"> <li>• Is the appropriate level of expertise needed for completion available in-house?</li> <li>• Are all the right technologies available in-house and are they reliable?</li> </ul>	<ul style="list-style-type: none"> <li>• The Project Leader should have the responsibility to make a choice between internal supply by a functional group, and external supply by, for instance, a Contract Research Organisation. At the next level, functional Teams should be able to make similar judgements</li> </ul>	<ul style="list-style-type: none"> <li>• Inadequate in-house expertise will lead to failure to complete Project tasks and eventually to registration failure.</li> </ul>

Health Check 5	Prompts	Commentary	Symptoms of failure
<p><b>What are the Project Metrics?</b></p> <p><i>What information is required to reassure management that the Project is on time, on budget, and meeting Product Profile?</i></p>	<ul style="list-style-type: none"> <li>• Is there adequate documentation of requirements and measures of success and are these agreed with Sponsors and Stakeholders, and External parties?</li> <li>• What are the chances of success and are these understood and explicitly accepted?</li> <li>• Is there a regular Senior Management review process covering future and past activities?</li> <li>• Is there a Communications plan, which highlights what to communicate to whom, how, and when?</li> </ul>	<ul style="list-style-type: none"> <li>• The Project Leader must be able to draw on a number of tools to help control the Project and demonstrate to the Sponsors that the Project is delivering to time, cost and Product Profile.</li> <li>• Metrics will variously include milestone dates, budget information (forecast vs. actual), decision logs (e.g. at each decision point in the Project Plan) and revised projections of likely Project commercial success to determine whether it is still within the allowable scope of the business case.</li> </ul>	<ul style="list-style-type: none"> <li>• Projects with no measurables are prone to time and cost overrun and failure to meet Product profile, with seriously impaired chances of commercial success.</li> </ul>

Health Check 6	Prompts	Commentary	Symptoms of failure
<p><b>Have contingency plans been drawn up to aid risk and issue management?</b></p> <p><i>What happens if Project events turn out unexpectedly?</i></p>	<ul style="list-style-type: none"> <li>• Have the potential scenarios that could compromise (or enhance) the project been identified and recorded?</li> <li>• Can preventative measures be taken?</li> <li>• Have alternative plans been drawn up for the most likely scenarios?</li> <li>• Does the Project Team evaluate emergent data expeditiously to determine whether an alternative plan needs to be adopted?</li> </ul>	<ul style="list-style-type: none"> <li>• There will always be uncertainty over the likely outcomes to Project tasks and to the changes in Corporate and environmental influences on the Business Case.</li> <li>• Likely risks and issues should be considered from the inception of the Project and contingency plans developed for the possible outcomes according to the emergent data.</li> </ul>	<ul style="list-style-type: none"> <li>• Failure to respond to simple situations will result in their escalation into issues.</li> <li>• Random reaction to emergent data that falls outside the expected finding will rapidly take the Project into unplanned areas out of the Project Scope, and ultimately lead to failure.</li> </ul>

Health Check 7	Prompts	Commentary	Symptoms of failure
<p><b>Is there attentive Management Review?</b></p> <p><i>How does senior management continue to demonstrate a commitment to the Project?</i></p>	<ul style="list-style-type: none"> <li>• Has Management, including the Project Sponsors, committed to success and approved the Project in all respects?</li> <li>• Has the priority within the overall Portfolio been reconfirmed?</li> <li>• Is progress consistently monitored against the agreed metrics - in partnership between both Project and contributing expert functions?</li> <li>• Is there a clear mechanism for highlighting issues and gaining acceptance for recommendations?</li> <li>• Are the outcomes of reviews and the associated learnings recorded and widely shared within the organisation?</li> <li>• Is Management sensitive to the unfolding and often unexpected needs of the Project and does it offer guidance and encouragement?</li> </ul>	<ul style="list-style-type: none"> <li>• Senior management should review the progress of the Project at appropriate intervals. It should draw on the appropriate Project Metrics, including plans and budgets. This is to ensure that the Business case and the emerging Project Profile are in alignment and that the appropriate priority for the Project within the overall Portfolio of Projects is not only maintained, but also communicated to the organisation at large. Important strategic decision points will include: <ul style="list-style-type: none"> <li>○ Commit to product type</li> <li>○ Commit to biological target</li> <li>○ Commit to lead series</li> <li>○ Commit to candidate medicine</li> <li>○ Commit to First Time in Man</li> <li>○ Agree Proof of Concept and Commit to Phase IIB</li> <li>○ Commit to Phase III</li> <li>○ Commit to Register &amp; Launch</li> <li>○ Commit to Lifecycle Management</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• A Project that is not attentively reviewed will suffer terminal decline, principally because of lack of sponsorship, loss of resource and uncontrolled change in scope.</li> </ul>

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Health Check 8	Prompts	Commentary	Symptoms of failure
<p><b>How do you manage interim review and closure?</b></p> <p><i>Are there mechanisms for capturing key learnings both about successes and failures at the end of the Project, or the intermediate stages of a Project?</i></p>	<ul style="list-style-type: none"> <li>• How do you set about capturing key learnings from the Project?</li> <li>• How do you feed these learnings back to the organisation?</li> </ul>	<ul style="list-style-type: none"> <li>• Encouraging the Project Team to function as a 'Community of Practice' and to reflect on the reasons for success or failure allows the organisation to move forward to the next challenge with Team members refreshed and motivated because preceding events have been properly closed out.</li> </ul>	<ul style="list-style-type: none"> <li>• Organisations learn little or nothing from the natural history of a Project and are destined to repeat mistakes time and time again.</li> </ul>