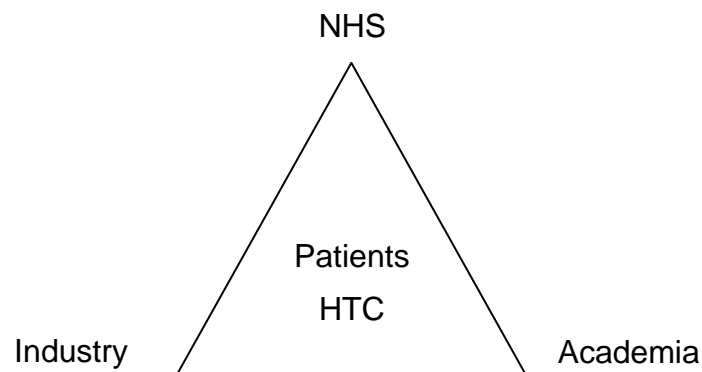


HEALTHCARE TECHNOLOGY CO-OPERATIVE WORKING GROUP



**FIRST REPORT TO HEALTHCARE INDUSTRIES TASK
FORCE STRATEGIC IMPLEMENTATION GROUP**

NOVEMBER 2005

Index

SECTION	PAGE
Executive Summary	4
1. Background	6
2. Requirement for Healthcare Technology Co-operatives (HTCs)	7
3. Definition of an HTC and its Outputs	7
[Figure 1. The Role of an HTC in the Innovation Landscape from Innovative Concept to New Product of Technology]	
3.1 <i>HTC Activities and Outputs</i>	8
3.1.1 Clinical Engagement	8
3.1.2 Articulated and Quantified Unmet Clinical Needs	8
3.1.3 Resources	9
3.1.4 Projects	9
3.1.5 Technologies	9
3.1.6 Dissemination and Uptake	9
3.1.7 Evidence	9
3.1.8 Evaluation Studies	10
3.1.9 Industry Support	10
3.1.10 Portal for Industrial and Academic Access to Clinical Specialisation	10
3.2 <i>Key Challenges for HTCs</i>	10
3.3 <i>HTC Characteristics</i>	10
3.4 <i>Interactions with Related Organisations</i>	11
4. HTC Pilot	12
4.1 <i>Purpose of Pilot</i>	12
4.2 <i>Duration of Pilot</i>	12
4.3 <i>Funding</i>	12
[Table 1. Proposed Indicative Funding for the <i>De Novo</i> Pilot]	
4.4 <i>Process for Recruitment of the Pilot(s)</i>	13
4.5 <i>Criteria for Evaluating Success of an HTC</i>	14
4.5.1 Organisational	14
4.5.2 Patient Benefits	14
4.5.3 NHS Improvement	15
4.5.4 Wealth Creation	15
5. Proposed Next Steps for the Working Group	15
6. Recommendations	15

SECTION	PAGE
APPENDICES	
1. HOW HTCs WOULD INTERFACE WITH EXISTING INFRASTRUCTURES AND ONGOING INITIATIVES	16
[Figure 2. Interfaces with Existing Organisations and Ongoing Initiatives]	
NHS Innovation Hubs, NHS Institute for Innovation and Improvement, Including the National Innovation Centre	16
Health Technology Device Programme	17
Clinical Research Networks Being Established via the UK Clinical Research Collaboration	17
Faraday/Knowledge Transfer Network Medilinks	17
Regional Development Agencies	17
Centre for Evidence-Based Purchasing	17
2. HTC WORKING GROUP TERMS OF REFERENCE AND LIST OF MEMBERS	18
HTC Working Group Terms of Reference	18
Working Group Members	18
3. LESSONS LEARNT FROM EXISTING ORGANISATIONS INCLUDING INTERNATIONAL COMPETITORS	19
General	19
Research Council Centre Funding	19
Australian Technology Co-operatives	19
BioMed HTC Centre, Bristol	19
Wound Healing Research Centre, Cardiff	20
Cornwall Medi-Park Ltd	20
UHCW Trust Incubation Centre, HT Evaluation Centre and HT and Innovation Park	20
4. FEEDBACK FROM STAKEHOLDER WORKSHOP	21
Question 1: We think this is the gap an HTC should fill: do you agree? If not, why not?	21
Question 2: How should an HTC interface with existing organisations and networks? How to minimise unnecessary overlaps?	22
Question 3: How would we measure HTC success?	22
General Issues	22
Linkages Identified	23
5. CRITERIA FOR DESIGNATION OF HTC STATUS	24
6. EXAMPLE OF HTC STRUCTURE	25
[Figure 3. Pictorial Example of a HTC Structure]	
References	27

Executive Summary

Background

At its first meeting the Healthcare Industries Task Force (HITF) Strategic Implementation Group (SIG) decided to establish a Working Group to make proposals for how the HITF Report recommendation for piloting a Healthcare Technology Co-operative (HTC) could be taken forward. Specifically, the Working Group was requested to produce an initial report to provide a definition of an HTC and its outputs, criteria for designation of HTC status and proposals for establishing a pilot and evaluating its success. In formulating its proposals, the Working Group has sought to learn from the experience of existing HTC-type organisations and articulate the gap in the evolving innovation landscape which HTCs would fill.

Definition of an HTC and its Outputs

An HTC is a clinician-led formal, but responsive, collaboration between clinicians, patients, academia and industry which acts as a focus for “technology pull” into the NHS. Based in an NHS Trust, it is a national resource established to address areas of unmet clinical need, where innovations in treatments and technologies have the potential to make a high impact by both reducing morbidity and improving quality of life for a large population of patients; and improving the effectiveness of the health and care services supporting them.

There are a growing number of networks and organisations in the innovation landscape which provide advice/co-ordination and with whom HTCs will interact. HTCs fill the gap of **providing capacity** to identify clinical issues from a front line service perspective and **deliver solutions** to address them on a national basis. They are distinguished by the emphasis they place on patient engagement and facilitating interactions with those seeking to address their needs.

The core activities and outputs of HTCs will include:

- strong clinical engagement established via a critical mass of collaborating clinical groups in other Trusts nationally, who will champion wide-spread change
- articulation and quantification of the unmet clinical need the HTC was established to address, with a prioritised list of issues
- provision of a physical base within a clinical setting which allows multi-disciplinary teams focussed on the issues to form and work together, including incubator support for small and medium enterprises (SMEs), spinouts and start-ups relating to the work of the HTC
- a ‘pipeline’ of new technologies, some of which may be realised in terms of formation and development of SMEs.
- dissemination and uptake of innovation and improvement in both practice and the essential underpinning technologies.
- provision of a robust and credible clinical evidence base (including incidence, prevalence, burden of disease and health economic data) to support decisions on whether to adopt new ways of working and product development.
- ability to respond rapidly to provide information to inform policy development.
- ad hoc projects, including evaluations of technologies and innovations relevant to their specialisation.
- provision of a portal for industrial and academic access to clinical specialists.

Proposals for the Pilot

Experience to date in establishing similar organisations indicates that there is a significant time-lag (of up to nine years) between set-up and delivery of innovative products.

It is proposed that a mixed model five-year pilot would be the best method of generating robust timely evidence on which to assess the business case for establishing a long term broader programme of HTCs. It would comprise a:

- *de novo* pilots in which the effect of core funding for a newly established organisation, developed from inception to the meet the HTC criteria described in this report, is evaluated. A fund of approximately £250K per annum would be required to fund a Business Manager, sessions for a Clinical Director and other staff (including Professions Allied to Medicine), ad hoc access to academic skills, core running costs and incubator space. **Subject to funding availability and receipt of suitable quality bids, the Working Group propose that there should be three *de novo* pilots.**
- booster pilots, in which the effect of provision of targeted funds to existing organisations to enable them to remodel themselves to meet the HTC criteria defined in this report would be assessed. An annual fund of £100K is proposed.

Both forms of pilot would be selected on the basis of open competition and require successful bidders to comply with defined governance and reporting arrangements.

Initial discussions with the relevant Research Councils, the Association for British Healthcare Industries (ABHI), Department of Health (DH), and the Department of Trade and Industry (DTI) funders indicate that it should be possible to establish a funding concordat, based on effective review processes and establishment of acceptable governance principles for HTC bids.

Evaluation of the Pilots

Criteria for evaluating the success of the HTC pilots are proposed in the report. These cover the following domains: organisational development; patient benefits; NHS improvement; and wealth creation. It is suggested that a Steering Group, with international representation from those with experience in similar initiatives, is established to review performance of the pilots individually and, as a whole, and to provide feedback to the HITF SIG and pilot funders.

Proposed Next Steps for the Working Group

To provide a final report to SIG by the end of February 2006 which:

- defines the corporate governance arrangements for the pilot HTCs, taking into account the need for transparency, probity and independence
- includes a draft Call for Tenders for the pilot, including implementation timetable
- proposes membership for the Tender Evaluation Panel and defines the process for peer review and decision on applications
- identifies options and recommends a mechanism for bringing together all the funding bodies, possibly via a Concordat. This will include the outcome of discussions with the devolved administrations, as there is a strong desire to confirm the HTCs as a UK-wide initiative.

Recommendations

The SIG is asked to:

- endorse the HTC concept and proposed piloting process defined in this report
- advise on the number of *de novo* pilots which should be funded
- authorise the proposed next steps for the Working Group.

1 Background

The Wanless Report (2002)¹ raised concerns that the NHS was a late and slow adopter of medical technology.

The Healthcare Industries Task Force (HITF) was convened in 2003 to enable the UK-based healthcare products industry to work with government to facilitate the introduction into the health and social care system of beneficial new technologies in an attempt to improve the situation. It defined the opportunities and developments needed to stimulate innovation and bring benefits for patients and health care service users, health and social care services and the healthcare technologies industry. Its report "Better Health through Partnership: a programme for action" was published in November 2004². It is one of several reports which highlight the benefit of improve public health and increased national wealth.

During the HITF process, Working Group 2 (which considered R&D and the Industrial Base) had identified a gap in the technology development process for healthcare technologies. It highlighted the tremendous scope for innovative approaches to treatment. However, it noted that developing these required a high level of interaction between clinicians and users of technologies, academia and the people and organisations inventing and developing the technologies, and that forums for developing such interactions were lacking. HITF was the key driver for bringing all parties together and the Healthcare Technology Co-operative (HTC) concept was developed to respond to this need. Recommendation 5 in the HITF Report was that: "Government and industry will work together to develop a suitable academic centre of excellence as a pilot HTC to pioneer specialist techniques in patient treatments in order to inform future development."

Also in 2005, the House of Commons Health Committee Report³ on the Use of New Medical Technologies within the NHS made a number of recommendations including that

- greater effort be made to strengthen the links between health and social services to ensure more effective roll out of new technologies into domestic and community settings;
- greater involvement of clinical champions was needed to sponsor the implementation of new technology; and
- improved techniques for determining the cost-effectiveness of new technologies were required.

Following the publication of the HITF report, the HITF SIG commissioned a Working Group to refine the concept of an HTC and how the recommendation could best be undertaken in the context of the evolving landscape (See Appendix 1), notably:

- the recent establishment of the UK Clinical Research Collaboration (UKCRC) and its Clinical Research Network (UKCRN)
- the new National Institute for Innovation and Improvement, having within it the National Innovation Centre
- NHS Purchasing and Supply Agency (PASA)'s new Centre for Evidence-based Purchasing (CEP).

The Working Group co-chaired by the Department of Health and ABHI held a series of meetings in September and October 2005. Its Terms of Reference and membership are at Appendix 2. The Working Group reviewed the current forms of linkage of industry (large enterprises and SMEs) with clinicians, investigated a number of HTC-like organisations and lessons learned in their establishment, and reviewed the experience of research councils in funding collaborative organisations. A summary of the lessons learned is at Appendix 3. The Working Group put forward its initial findings to a Stakeholder Workshop involving

participants from DH, NHS, PASA, Regional Development Agencies (RDAs), NHS Innovations Hubs, clinicians, patient representative and a range of companies, including SMEs. A summary of the feedback from the Stakeholder Workshop is at Appendix 4. This Report summarises the Working Group's findings and documents its proposals to pilot the HTC concept.

2 Requirement for Healthcare Technology Co-operatives (HTCs)

Having reviewed the innovation landscape, the Working Group concluded that:

- there were multiple mechanisms for “technology push” into the NHS, but few for clinician-led “technology pull” into the NHS
- there were a growing number of networks and organisations which provide advice/co-ordination, but a gap for an organisation which has the capacity for defining clinical issues, delivering solutions to address them and providing national co-ordination
- innovation in individual technologies aimed at improving the diagnosis, monitoring or delivery of health status are required, especially in those with chronic conditions many of whom will be treated in the community and have historically had a low profile with manufacturers. These technologies may be simple devices or may involve the interactions of a number of constituent elements in relatively complicated systems (e.g. for telecare)
- there were clinically significant areas, which were highly important in terms of morbidity or quality of life issues for a large number of patients (and consequently cost to the NHS), where designing new devices had the potential to significantly improve health outcomes for a large number of patients. These were likely to be found in areas that crossed from healthcare into social care delivery. However, these tended to reflect clinical areas which were not glamorous (e.g. urological incontinence) and did not offer the opportunity to publish research papers in prestigious medical journals which would make them naturally attractive to researchers.

The Working Group identified this as a place where unmet needs were likely to continue unless addressed through an organisation, such as an HTC, specifically positioned to fill this gap. The participants of the Stakeholder Workshop were unanimous in their agreement that this was an important gap which needed to be filled.

There was a need for a mechanism to energise and focus interest in unglamorous and neglected areas that would give status and recognition to those championing the cause, and bring funding for activities essential to raising awareness among healthcare providers, researchers and industry.

It was concluded that HTCs could provide the kind of collaborative environment that has worked most successfully for these kinds of technologies in the past. However, rather than waiting for them to ‘emerge’ serendipitously, there is a need for HTCs to be supported at their outset with core funding and a branding which will enable them to be formed quickly and efficiently in the areas where they are most needed.

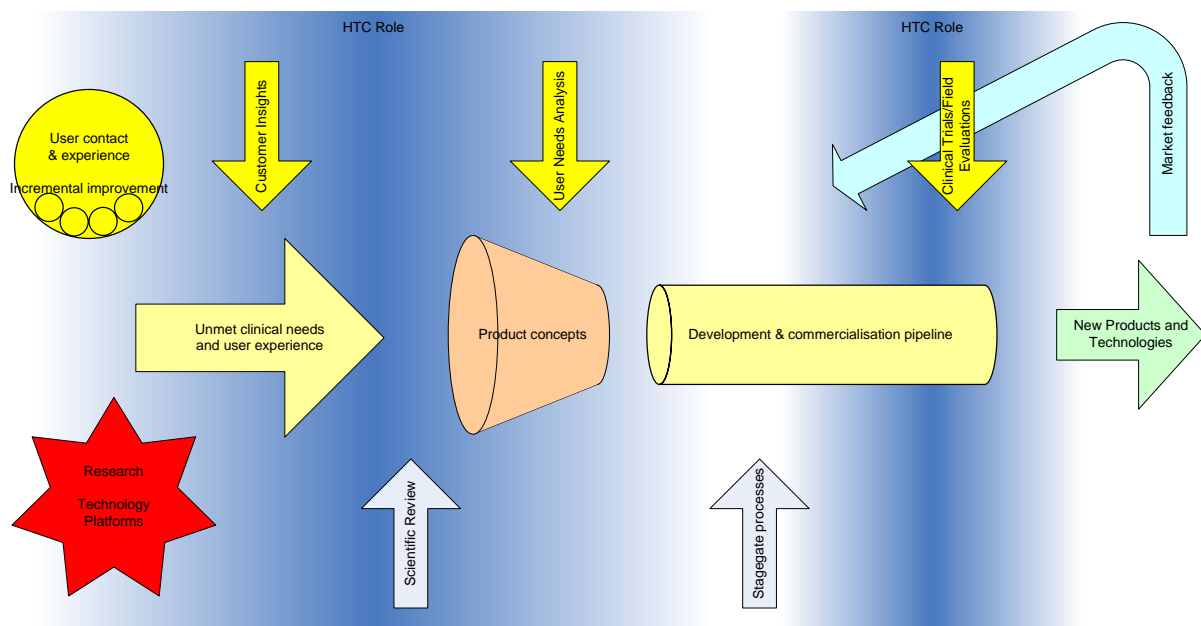
3 Definition of an HTC and its Outputs

The Working Group defined an HTC as a clinician-led formal, but responsive, collaboration between clinicians, patients, academia and industry. It is a national resource which is focused on delivering results and is established to address areas of unmet clinical need where innovations in treatments and technologies have the potential to make a high impact by both reducing morbidity or improving quality of life for a large population of patients and improving the cost effectiveness of the health and care services supporting them.

Figure 1 illustrates the proposed role of an HTC in the innovation landscape. An HTC will provide a collaborative environment which will be involved throughout the technology and the product development process by establishing a number of close, long-standing clinical and technical collaborations and have a particularly important role at two stages:

- technology and product concept: bringing clinical insights into formulation of need where a close collaboration of partners can develop, test and improve concepts in a relatively short time
- clinical evaluation: trialling a completed development in a clinical environment in a very timely and cost effective way through the mutual understanding of both the trial risks involved and the trial questions.

Figure 1. The Role of an HTC in the Innovation Landscape from Innovative Concept to New Product or Technology



3.1 HTC Activities and Outputs

While the specific activities of any individual HTC will depend on the demands of its specific area of specialisation, it is anticipated that there will be a core of activities common to all HTCs.

3.1.1 Clinical Engagement

Its strong engagement with the relevant clinical specialists is the main way in which an HTC differs from almost every other form of technology and innovation organisation. This will be met through a direct involvement in the HTC of active clinical staff (including scientists and other involved in service delivery). In order to protect the time of these staff in contributing to the research agenda, the HTC will have funding to pay for dedicated sessions for clinical staff. While these may increasingly be funded through research projects as this portfolio develops, it will be necessary to maintain a core level of staffing outside specific projects, and core funding will enable a dedicated clinical staffing from the start of the HTC.

3.1.2 Articulated and Quantified Unmet Clinical Needs

An HTC will articulate the voice of the customer (clinician, theatre nurse, patient, etc) to attract business to focus on clearly identified clinical need and identify and respond to under-satisfied patient needs, “champion the cause” and prioritise issues for attention against objective criteria.

3.1.3 Resources

It will provide a physical base within a clinical setting which allows teams focussed on the specialisation to form and work together and produce a cohort of practitioners with an in-depth, research based knowledge of the condition and responses to it and hence high quality informed input to product development. In addition, it will develop a skill base in issues relating to the application of innovation within the area of specialisation and support the provision of specialist training to enable the effective roll-out of HTC derived innovations

3.1.4 Projects

It is anticipated that projects will be a major activity of the HTC and the main source of funds in addition to its core funding. This will require assembling research consortia, putting together proposals in response to calls from funding bodies and then running the research projects. These projects will provide the principal means to extend the collaborations within the HTC, based on funding for additional partners to become involved: these partners will be clinical, academic and industrial, and may well be international as well as UK-based, depending on funding sources.

It is likely that the HTC will take the lead in driving an awareness of the need for research in its clinical specialisation, and on the basis of an established international profile, will tend to emerge as a focus for such research proposals.

3.1.5 Technologies

This will include supporting the development of a 'pipeline' of new technologies and treatments, some of which may be realised in terms of formation or development of SMEs, and horizon scanning newly appearing technologies which might be applicable in the field whilst recognising that the clinical problem might not need high tech solution. In addition, it will accelerate the adoption of innovations which will improve the health and quality of life of patients.

3.1.6 Dissemination and Uptake

Dissemination of innovation and improvement in both practice and the essential underpinning technologies is one of the primary purposes of HTCs. This dissemination can take a number of forms:

- traditional academic dissemination of project results, through conferences and published papers
- holding seminars on best practice
- instituting formal training courses for health professionals and technology users and developers, both health providers and industry
- establish a national (and ultimately, international) status as a centre of world-class expertise in its area of specialisation.
- build networks of clinicians, companies and academics with a shared interest in meeting these needs through the development of innovative technologies and treatments
- use its network as a basis to a programme of dissemination which would help accelerate the uptake of innovative technologies and best practice.

3.1.7 Evidence

HTCs will provide a robust and credible clinical evidence base (including national incidence, prevalence, burden of disease and health economic data) to support decisions to adopt new ways of working and product development in their field of expertise. They will develop a resource of specialist skills and knowledge, both at the core and through the network of collaborators, which can respond rapidly to requirements of policy makers for information to

support development of policy and other initiatives undertaken in the UK/England (and other) health services.

3.1.8 Evaluation Studies

The skills of the HTC in understanding the use of technologies in their area of specialisation, and their contact with a significant body of patients mean that HTCs will be extremely well placed to undertake evaluations of technologies and innovations relevant to their specialisation. These could be commissioned by partner businesses or NHS bodies [e.g. National Institute for Health and Clinical Excellence (NICE), CEP].

In conducting studies of this kind, HTCs are likely to link up with external organisations which have specialist skills in topics such as health economics and systems modelling, which are necessary to evaluation studies but which the HTC would not require on a full time basis.

Such studies would be usually be funded by the commissioning organisation and conducted according to their usual quality standards.

3.1.9 Industry Support

This will include the provision of incubator support for SMEs, spinouts and start-ups relating to the work of the HTC and its area of specialisation. It may also include undertaking work for specific businesses, such as undertaking specific testing or evaluation studies on a contract basis.

3.1.10 Portal for Industrial and Academic Access to Clinical Specialisation

It will establish a credible portal for those with interests in their specialisation, both in UK and internationally, providing access to Key Opinion Leaders and expressing the authentic “voice of the customer”, and providing well-managed access for companies to patients with whom to assess the safety and effectiveness of developing technologies and treatments.

3.2 Key Challenges for HTCs

Based on the experience of existing HTC-type organisations, the key challenges for the HTC would be:

- provision of strong effective leadership and gaining recognition for the brand
- incentivising high calibre research staff into clinical areas that are perceived as low impact and unglamorous
- the necessity of safeguarding clinician (or other healthcare worker) time to enable them to carry out research
- fostering truly collaborative working between different centres, rather than competition
- absence of a culture of working collaboratively with industry in some parts of the NHS
- the short-term and specific nature of most funding compared with the long term view necessary to see innovative concepts developed into innovative products
- the prohibitive cost of clinical trials for SMEs
- a perception of lack of credibility of industry-funded technology evaluation studies.

3.3 HTC Characteristics

The criteria for designation of HTC status are at Appendix 5. Healthcare technologies are exceptionally diverse and used in very different circumstances by a broad range of users. Recognising this, the Working Group considered it important that descriptions of the potential form an HTC could take should not be overly prescriptive: an illustrative example

which would expect to deliver these outputs is presented in Appendix 6. However, as guidance, it would be expected that an HTC would:

- be based within an NHS Trust, probably with direct links to a specific clinical department
- have links with:
 - a critical mass of collaborating clinical groups in other Trusts nationally;
 - appropriate academic departments;
 - patient and disease related charities and support groups; and
 - new product development sections of companies.
- provide national co-ordination of endeavours to address the unmet clinical needs and have a clear “brand”
- have core resources consisting of:
 - strong leadership through a Clinical Director, supported by a Chairman and an Executive Board representing stakeholders and funders/supporters;
 - a Business Manager and access to staffing with a capacity and credibility to develop, propose and manage a number of collaborative projects and dissemination activities;
 - ad hoc specialist research staff from disciplines where there will be highly specific domain knowledge associated with undertaking research via links with specialist departments. These could be involved either for a short intensive period or in sessions provided over a longer period of time on a regular basis; and
 - protected time for clinicians/other healthcare workers/care workers.
- have the potential to provide space for incubator facilities for SME or large company spin-out collaborators to develop new technologies and therapies in close collaboration with their clinical colleagues
- have transparent and robust corporate governance arrangements. This is essential because, with an HTC placed within an NHS Trust, the organisation will potentially be involved in the development, evaluation and purchase of medical devices. It is proposed that the HTC be set up as a Company Limited by Guarantee[†].

3.4 Interactions with Related Organisations

This aspect is covered in detail in Appendix 1. Although there are many organisations and initiatives with which HTCs would be expected to form linkages, few are concerned specifically with technology pull, and this is the recognised need for HTCs to fill.

The NHS Institute for Innovation and Improvement and NHS will be accessible to provide advice on innovations and intellectual property (IP). HTCs will be expected to operate in the legal framework of IP management within the NHS, with input from the National Innovation Centre and oversight by the Innovation Hubs. HTCs will be able to bid for appropriate funding through existing funding streams from DH (e.g. Health Technology Devices Programme), DTI, Research Councils and charities etc, and those provided through RDAs. HTCs should be able to turn to the UKCRN for assistance with multi-centre trial development and approvals; HTCs should find Knowledge Transfer Network Medilinks a helpful source for SME advice. HTCs and CEP could co-operate to ensure that good data are obtained on the economic impact of the new technology.

[†] This follows the precedent set successfully by many of the NHS Innovation Hubs

4 HTC Pilot

4.1 Purpose of Pilot

The purpose of the HTC pilot would be to act as a prototype to:

- bring the relevant parties together and assess the viability of the HTC concept against pre-defined metrics
- act as an “evolutionary precursor” to test out the framework, methodology and plan, recognising that ultimate HTC outcomes might not be measurable until some time later than the pilot assessment period.

The Working Group considered a variety of forms for the pilot and noted that pilots were usually viewed as the opportunity for a “quick and dirty” proof of concept study. The long time lag between establishment of an HTC and the time at which it would be able to demonstrate tangible outcomes did not lend itself easily to this concept; the Working Group was particularly mindful of the Australian experience in which the consensus from around 50 technology co-operatives in a diverse range of fields, is that an average of nine years was needed to clearly demonstrate success. (See Appendix 3)

Consideration was therefore given to whether the pilot should be constructed around one of the existing HTC-type organisations such as this to provide the opportunity to reduce the timeframe for the pilot. However, this was considered to have the disadvantage of not permitting the evaluation of the impact of initial core funding, viewed as key to the success of an HTC, in areas which were absent at the time of establishment of these organisations.

It was concluded that a mixed model pilot would be the best method of generating robust, timely evidence. It is proposed that it comprise a:

- *de novo* aspect in which the effect of core funding for a newly established organisation, developed from inception to meet the HTC criteria described in this report, is evaluated
- booster aspect, in which the effect of provision of targeted funds to existing organisations to enable them to remodel themselves to meet the HTC criteria defined here would be assessed. (Note: this would not be funding to carry on business as usual.)

Both forms of pilot would be selected on the basis of open competition and require the successful bidders to comply with defined governance and reporting arrangements.

4.2 Duration of Pilot

The Working Group concluded that the pilot should run for five years. Evaluation of the success of the *de novo* pilot should be carried out after 3 years with interim annual reviews, at which point, progress would be monitored against pre-defined milestones and metrics. It is anticipated that the pilot HTC would have responded to changing circumstances in the industry and health service practice during this period, and assessment of the metrics will allow for this type of evolution of the concept.

4.3 Funding

It is proposed that the *de novo* pilot provides core funding in areas identified as critical to success. Indicative figures and proposed funders are presented in the table below.

Table 1. Proposed Indicative Funding for the De Novo Pilot

<i>Resource</i>	<i>Comments</i>	<i>Cost Range (EK/yr)</i>	<i>Funding Sources</i>
Clinical Director	(@ 2 sessions)	20	DH R&D
Business Manager	(outward facing)	50	DTI
Clinical Sessions	(including PAMs)	25	DH R&D
Ad hoc access to academic skills	(e.g. Health Economists, Statisticians, Biotech etc)	50	Relevant Research Councils
Core Running Costs	(inc clerical staff and progress chasing etc)	50-100	RDA, Charity, ABHI**
Incubator space	(including basic business support facilities and staffing)	??	RDA
Total		~250	

** Acting as a collecting agency for industry members which wanted to support the HTC

Initial discussions with the relevant Research Councils, ABHI, DH and DTI have confirmed their support for the proposed core funding arrangements and indicate that it should be possible to establish a funding concordat, based on effective review processes and establishment of acceptable governance principles for HTC bids. However, the English Department of Health can only provide funding to English organisations. The Working Group considered that the HTC initiative should be UK-wide and hence that discussions should be initiated with the devolved administrations to assess their interest in participating in the pilot.

It is important to recognise that the funding provided in the pilot covers only core resources. The HTC will need to acquire additional funding (e.g. for projects via bidding to the Medical Research Council, Engineering and Physical Sciences Research Council, Economic and Social Research Council, Biotechnology and Biological Sciences Research Council, DTI Technology Programme, European Union, charities etc.) and an important component of the pilot is evaluating how successful they are at doing so.

An annual fund of £100K is proposed for the booster pilots.

Further consideration is required of the mechanism for collection and dispersal of funds e.g. whether it should be via establishment of new, or extensions to, existing concordats.

4.4 Process for Recruitment of the Pilot(s)

It is proposed that the HTC Working Group develops a Call for Tenders (to include indicative funding available) to be advertised in nationally recognised journals, such as the British Medical Journal, and in the Official Journal of the European Communities. It is recommended that HTCs are organised as Companies Limited by Guarantee, building as far as possible on the experience and structures of the NHS Innovation Hubs, especially in the arrangements for governance and formal organisation.

To meet the criteria for HTC status (Appendix 5), the pilot will need to be in a clinical speciality with a high degree of unmet need for which technologies which could be met by UK industry, and supported by UK academic expertise. Chronic disease management, infection control and disability rehabilitation are examples of areas for which an HTC would be beneficial, but other areas would be eligible for consideration.

Subject to the receipt of suitably high quality proposals, the Working Group considered that it would be beneficial to have more than one *de novo* pilot (and propose three), although the feasibility of this would be dependant on the availability of funding identified to support the piloting process. This will be clarified in the final report to the SIG.

It was recognised that the HTC Working Group would not be able to evaluate the tenders because of actual or potential conflicts of interest for some of the Working Group members.

Therefore it is proposed that a Tender Evaluation Panel (TEP) be constituted to include membership from the funders, industry trade association(s), academia and patients.

4.5 Criteria for Evaluating Success of an HTC

A Steering Group, comprising an international team of people with experience in similar activities, would be established to review performance of the pilots on an annual basis and to provide feedback to the HITF SIG, and funders.

Criteria for evaluating the success of an HTC will need to be both quantitative and qualitative. It was recognised that it is likely that there will be some variation in the nature of the success criteria depending on the specific nature of the HTC and its area of specialisation. In addition, as the timeframe for many of the outputs will be relatively long, proxy indicators of success or 'added value' will be needed. The booster pilot would be assessed on the basis of clearly defined current deficiencies with metrics for assessing the effectiveness of funding to move the organisation to HTC success. They would comprise a subset of the full evaluate criteria.

Examples of success criteria include:

4.5.1 Organisational

<i>Criterion</i>	<i>Pilot Target (3 yrs)</i>	<i>HTC Target (10 years)</i>
Income generation	Double Core funding	Core funding <25%
Met all initial business plan targets	✓	
Evidence of national and international recognition as centre of expertise	✓	
Publications	XX conference papers	YY Conference papers NN journal papers
Membership of HTC by relevant UK stakeholders: industry and healthcare centres	✓	✓
Evidence of satisfaction of members (e.g. clinicians, industry, academics, RDAs, DH and patients) with services of HTC as a measure of the success of the model as a way of working	✓	✓
Number and range of NHS organisations, industrial players and academic centres undertaking evaluation/trial/development activity increases above baseline	✓	✓

4.5.2 Patient Benefits

<i>Criterion</i>	<i>Pilot Target (3 yrs)</i>	<i>HTC Target (10 years)</i>
Projects addressing significant unmet patient needs	✓ (limited numbers)	✓ (higher numbers)
Improvements to clinical practice/service delivery and organisation e.g. reduction in time spent in hospital or time with health professionals; reduction in drug therapy dependence; fewer invasive tests; patient-perceived improvements in health status; improvements in patients/carers satisfaction with the health care delivery; improvement in speed of diagnosis		✓
Clinician and/patient satisfaction for new products arising from HTC activities		✓
Demonstrated patient welfare improvement of greater than £xxM from results of HTC work/projects	(demonstration of potential benefits)	✓
Direct involvement with xx% of UK patient group through HTC network	✓	✓
Projects with the potential to deliver improved patient benefits at national level (quality of life, earlier diagnosis and treatment, better outcomes etc.)	£xM/yr	£5xM/yr

4.5.3 NHS Improvement

<i>Criterion</i>	<i>Pilot Target (3 yrs)</i>	<i>HTC Target (10 years)</i>
Sample audit of change in practice in local NHS departments to adopt HTC-derived best practice and models to estimate financial and performance impact on local NHS		✓
Evidence of widespread change in practice in NHS departments to adopt HTC-derived best practice and models to estimate financial and performance impact on NHS		✓
Improved satisfaction of NHS clinicians in response of industry to "pull" technology needs	✓ (low level change to be anticipated)	✓
Impact of evidence provided by an HTC to relevant policy/decision making	✓	✓

4.5.4 Wealth Creation

<i>Criterion</i>	<i>Pilot Target (3 yrs)</i>	<i>HTC Target (10 years)</i>
Number of NHS/Industry/academic collaborative projects increasing above baseline HTC collaborator activity	✓	✓
Spin-out/start-up jobs created in HTC contacts	(possible, not necessary)	✓
Number of Patents	(✓)	✓
Scale and value of new business opportunities arising		✓
Number and sales value of new products to market in which HTC have been involved or intervened		✓
Number (or growth in activity) from inward investors in HTC	✓	✓

5 Proposed Next Steps for the Working Group

Subject to the views of the SIG, the next steps for the Working Group would be to provide a report to SIG by the end of February 2006 which:

- defines the corporate governance arrangements for the pilot HTCs, taking into account the need for transparency, probity and independence
- includes a draft Call for Tenders for the pilot(s), including implementation timetable
- proposes membership for the Tender Evaluation Panel defines the process for Peer Review and decision on applications
- **identifies** options and recommends a mechanism for bringing together all the funding bodies, possibly via a Concordat. This will include the outcome of discussions with the devolved administrations, as there is a strong desire to confirm the HTCs as a UK-wide initiative.

6 Recommendations

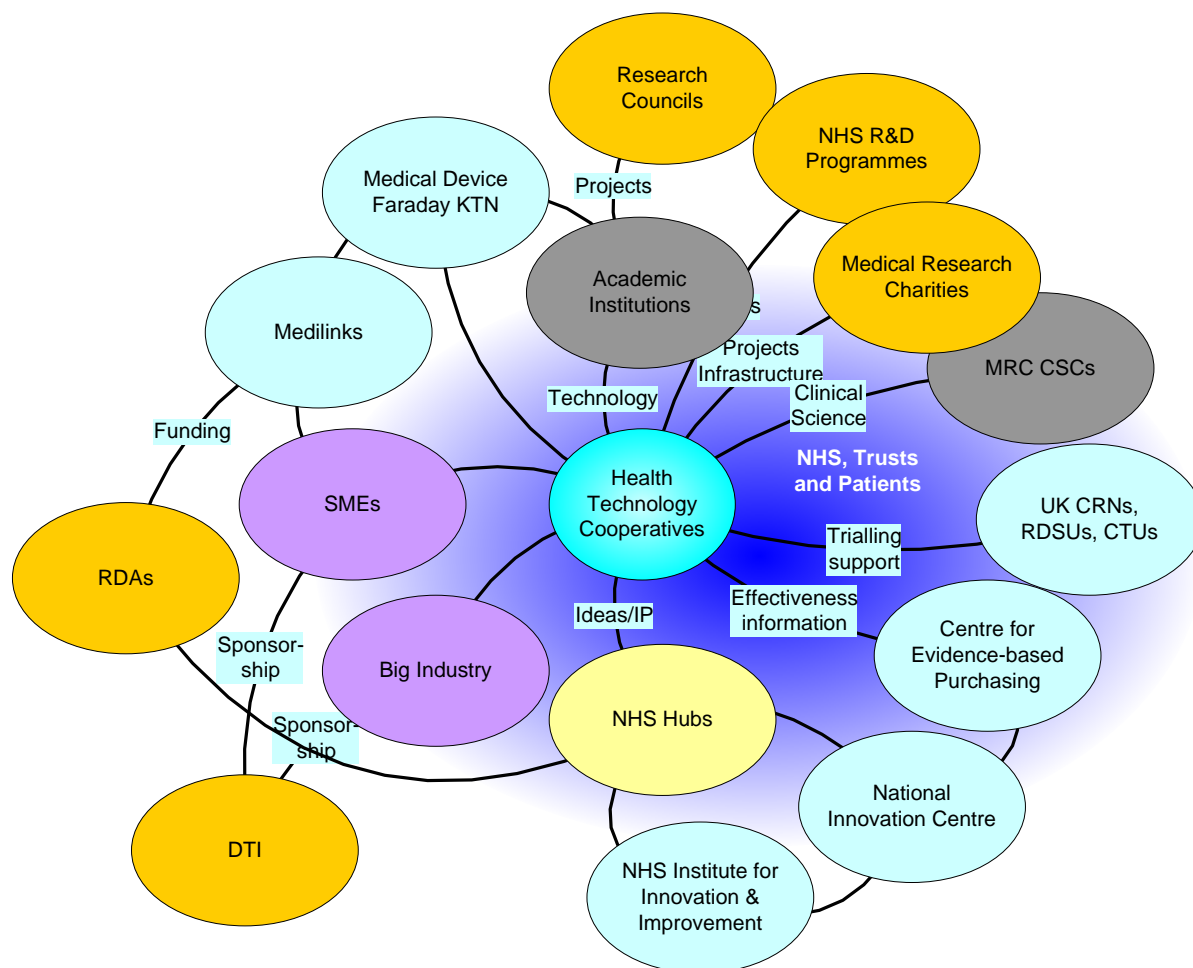
The SIG is asked to:

- endorse the HTC Concept defined in this report
- give a view on the number of *de novo* pilots which should be funded
- authorise the proposed next steps for the Working Group.

HOW HTCs WOULD INTERFACE WITH EXISTING INFRASTRUCTURES AND ONGOING INITIATIVES

The healthcare research and innovation space is complex and involves a number of initiatives and organisations with which the HTCs would be expected to form linkages to realise their full potential impact.

Figure 2. Interfaces with Existing Organisations and Ongoing Initiatives



NHS Innovation Hubs, NHS Institute for Innovation and Improvement, Including the National Innovation Centre

HTCs are expected to provide national centres of expertise. While they will almost certainly have close personal links with their local NHS hub or hubs, it is essential that they are accessible to all NHS inventors who have interests in their area of specialisation. Co-ordination of such linkages is likely to be supported through the NHS Institute, although all the hubs are developing their own exploitation channels and probably have the capacity to make such linkages directly.

The NHS Institute is addressing a number of specific areas identified for improvement and innovation. Where these overlap with an HTC's specialisation, it is anticipated that the NHS Institute will become directly engaged with the HTC to use the specific knowledge and skills of both its own staff and those of its network of collaborators.

Where HTC's produce high impact innovations which need additional development work or trialling, they are likely to get into discussion with the National Innovation Centre (NIC) within the NHS Institute, which may be able to provide resources and funding to support later stage development and uptake of the innovations. Equally, where the NIC encounters an innovation which is close to the area of specialisation of an HTC, it may well work with the HTC to find the most effective way to realise this innovation.

Finally, HTC's would be expected to be supported by the network of NHS Innovation Hubs to protect and exploit effectively and efficiently the IP arising from their work.

Health Technology Device Programme

HTC's are likely to use this (and similar funding programmes from DH or the research councils) as a source of funding for their projects.

Clinical Research Networks Being Established via the UK Clinical Research Collaboration

It is anticipated that HTC's will accumulate a great deal of specialist knowledge on trialling innovations relevant to the particular clinical focus of the HTC and be a key resource for iterative development of products involving very close working between companies and clinicians. The HTC will be expected to run a number of clinical trials and will develop its own expertise in this area. However, the HTC would be expected to form strong links with the UKCRC's Clinical Research Network (topic specific or generic infrastructure) for:

- support in multi-centre trial development and approvals
- development of and access to appropriate specialist staff and skills, especially in designing trials
- finding and establishing links with other potential trial collaborators.

Faraday/Knowledge Transfer Network Medilinks

As national centres for their specialisations, it is expected that HTC's will work with industry from across the UK. While it is recognised that local SMEs will have particular advantages (e.g. in terms of being able to establish incubator units in the HTC), the network activity of HTC's can be effectively increased by a factor of ten by using the established linkages already in place through the Medilinks, especially through their national co-ordination activity which is supported by the Medical Device Faraday KTN.

Regional Development Agencies

HTC's can provide the kernel of a local healthcare cluster. It is anticipated that RDAs will be an early part of the funding programme for an HTC, and will have particular interest in the incubator concept and support for the SME units which become involved.

Centre for Evidence-based Purchasing

HTC's will develop considerable expertise in the utility of treatments and technologies in their specific area. It is anticipated that they will involve health economist skills in their centre, either directly or through partner organisations.

This should enable the HTC's to develop specialist skills and resources which could be contracted by the CEP to provide high quality information on the effectiveness of technologies and devices in this area with greatest efficiency.

While one of the advantages of an HTC is the relatively immediate knowledge and skills it could offer, forward visibility of such requirement will certainly support the overall efficiency of the HTC, and it is anticipated that there will be a good working relationship between specific CEP staff with responsibilities in this area.

HTC WORKING GROUP TERMS OF REFERENCE AND LIST OF MEMBERS

HTC Working Group Terms of Reference

To provide the HITF Strategic Implementation Group (SIG) with:

- a fully worked-up definition of an HTC and its outputs
- proposed criteria for designation of HTC status
- an options appraisal of the process for selection of the pilot, with recommended approach
- proposed criteria for evaluating the success of the pilot
- options for funding the pilot, with recommended approach
- proposals on next steps should the pilot be deemed successful.

The proposals presented to the SIG will include a project plan to be delivered by 11 November 2005 and be informed by a consideration of:

- how HTCs would interface with the clinical research networks being established via the UK Clinical Research Collaboration
- ongoing initiatives, to ensure that an existing mechanism for delivery of HTCs-type outputs is not already available or could easily be adapted
- lessons learned from any existing HTC-type organisation, including international comparators
- how HTCs would interface with the Devices Evaluation Service and NHS Institute for Innovation and Improvement, including the National Innovation Centre, Faraday/Knowledge Transfer Network, Medilinks and Health Technology Device Programme
- effective interfaces with Innovation Hubs and Regional Development Agencies' Terms of Reference.

Working Group Members

Members		
Noreen Caine	DH RDD	
Tony Davis	Medilink West Midlands	
Sue Dunkerton	Medical Device Faraday KTN	
Jill Dhell	DH RDD	
Martin Ferguson-Pell	RNOH Stanmore	
John Hand	EPSRC	
Sarah Haywood	DTI Bioscience Unit	
Robert Morgan	Smith & Nephew Research Centre	
Allan Ritchie	DePuy International	
George Sarna	MRC	
Oliver Wells	ABHI	Co-Chair – Industry
Louise Wood	DH RDD	Co-Chair – DH
Observers		
John Jeans	GE Healthcare	
John Wilkinson	ABHI	
Doug Yarrow	BBSRC	

LESSONS LEARNED FROM EXISTING ORGANISATIONS INCLUDING INTERNATIONAL COMPARATORS

General

- The absolute importance of leadership. All examples worked because of strong, driven leadership - often one motivated individual.
- Need for security, certainty and duration of funding to provide the environment in which creative innovation work can happen. A number of examples were precarious because they didn't have that.
- To achieve success ... you must have absolute clarity of outcomes being sought.

Research Council Centre Funding

- Importance of leadership and governance structures.
- Clarity on whether funding is provided solely for pump-priming/building capacity or as a long-term commitment.
- Maintaining flexibility as the “goalposts” changed over time.
- Need for effective risk management.
- Avoiding diversity in goals between “different masters”.
- Recognise the challenges of artificial groups (or “forced marriages”).
- Engagement in priority setting.

Australian Technology Co-operatives

- The model works very successfully but it takes a long time to demonstrate success. Experience from over 50 co-operatives through a period of 15 years has demonstrated that it takes on average nine years to clearly demonstrate success.
- The ethos of existing as a “co-operation” is essential to the success of the venture. In particular, they do not subscribe to the concept of identifying a single elite organisation.
- The importance of having strong governance structures through contractual processes that focus on the outcomes rather than process detail.
- Rigorous reviewed of applicants by Review Panels consisting of academics, venture capitalists, industrialists and a research grant allocator.
- Successful applicants subjected to review for specific objectives at varying timescales and are also required to submit reports.
- Some co-operatives are so successful they launch themselves independently after some time; others naturally “run out of steam” and come to an end.

BioMed HTC Centre, Bristol

- Length of time required to set up such an organisation under current conditions.
- Need to find ways to retain knowledge of research staff.
- Need to avoid Centre's resources being annexed by the local Trust.
- Value of close collaboration with the Medical Device Faraday Partnership.

Wound Healing Research Unit, Cardiff

- Potential distraction of Director resource into constant search for funding.
- Need for credibility branding in an area where there is limited scope for high impact academic publications or ability to meet standard academic success criteria.

Cornwall Medi-Park Ltd

- Resourcing to balance facility development with supporting infrastructures.
- Need for individual incubator facilities.

UHCW Trust Incubation Centre, HT Evaluation Centre and HT and Innovation Park

- How much can be done by a CEO of a Trust where there is good local support infrastructures?

FEEDBACK FROM STAKEHOLDER WORKSHOP

After a presentation on the Working Group's concept of an HTC, delegates worked in groups to debate three questions (see responses below). Their feedback is summarised below.

There was unanimous agreement that there was a need for HTCs

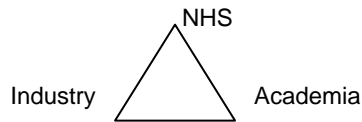
Question 1: We think this is the gap an HTC should fill: do you agree? If not, why not?

- Yes, there is a gap.
- HTCs possibly have a best-fit with longer term clinical problems as opposed to acute issues.

Unglamorous parts of treatment – chronic conditions – will probably come out on prioritisation. But don't discount high profile high impact areas.

- Be patient-led. This is a unique place for HTCs.
- Analyse the need:
 - carry out economic analysis of the market to identify;
 - match clinical problem with ability to capture newly emerging technologies but need to recognise may not need high-tech solution for problem;
 - assess what is the industry and academic capacity.
- Must be outcome driven.
- People in community with disabilities – no voice but are numerous up and down the country. Very difficult to distill into unit's ability to respond to their needs unless HTC is defined by the outcome.
- There must be a mechanism for capturing innovative technology ideas that are out there: There is lots of push but not much pull.
- Clear need for incentives and different ones for different constituents (clinical, industry, patients, academics).
- One organisation to champion a need – not just whole load of stakeholders brought together.
- Needs national coordination centre to co-ordinate activity and for longer term thinking.
- Continuation of funding – more than 3 year's funding necessary. Some will take long time to bring in.
 - long term funding;
 - realism – cost of clinical trials.
- What difference will it make to adoption of innovative products within the healthcare system? Must bring in healthcare commissioners eg. PCTs to be an integral part to enable this.

Question 2: How should an HTC interface with existing organisations and networks? How to minimise unnecessary overlaps?



- An HTC will have to interact with one or all of the existing stakeholders at one time or another.
- HTC status must equate to a clear brand/vision.
- Co-ordination and collaboration through a national network needed to ensure uptake. Need an overarching group to guide the other players, with teeth to persuade others to take action.
- National level clinical champion; must have at least one champion – possibly one from each of industry, NHS and academia.
- Hub with strategic facilitator; regional delivery/spokes; local nodes.
- If it was clinician-focussed and clinician-time-focussed and disease-led this would make it unique. Needs 30-50 clinicians to change things for SMEs.
- Carrying out economic assessment impact would be unique.

Question 3: How would we measure HTC success?

- Overarching aims are: patients' welfare, health service innovation, wealth creation.
- Have to decide whether measures are short or long term. They could be quantitative or qualitative:
 - measurement of quality of life/ patient benefit;
 - measurement of cost of problem/health care economics;
 - new technologies/ new products to market;
 - National outcomes impact;
 - Depth of industry coverage;
 - finance outcomes: work created, jobs, sick days etc (based on regional ONS figures);
 - critical mass of multidisciplinary clinicians;
 - pool of patients for clinical trials;
 - ratio of funding buckets;
 - access to key opinion formers;
 - quality of life tools: cost vs. quality of outcomes;
 - % of patients treated with new products/processor;
 - publications;
 - ratio of funding.

General Issues

- Independence: conflict between having the role of product developer while being located within a purchasing organisation.
- It needs to bring together the potentially conflicting goals of Regional Development Agencies and NHS service organisations.

- Timescales:
 - the need for long term funding and the inevitability of outcomes taking a long time to be delivered;
 - the difficulties this presents for measuring the success of the pilot(s).
- Competition – incubators will be competing against each other.
- The potential for an HTC to reinforce the outputs it has and lead to increased and faster uptake of new technologies by the health service.
- The potential for choosing a high priority broad cross-cutting issue such as hospital infection or disability.

Linkages Identified

- HTC role in enabling linkages particularly with respect to emerging technologies.
- The role of the National Institute for Innovation and Improvement.
- The need to involve the Royal Colleges.

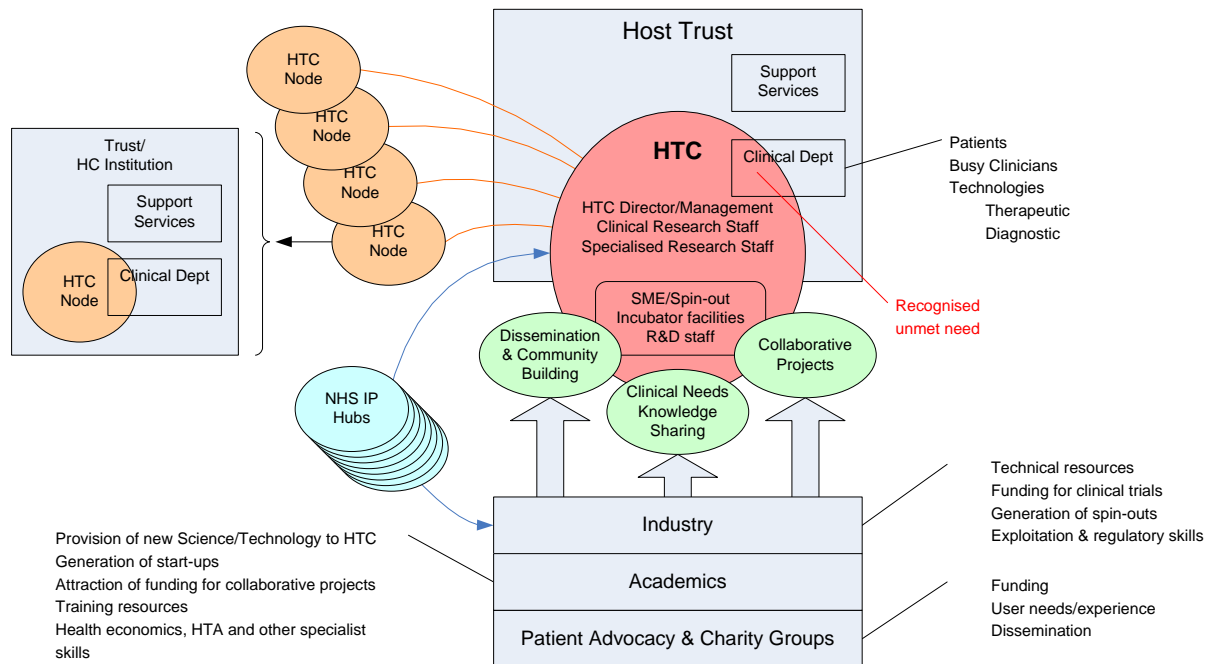
CRITERIA FOR DESIGNATION OF HTC STATUS

An HTC will be:

- a national resource, with programmes led by one or more leading clinical investigators
- led by clinicians with a focus on a particular clinical area
- demonstrate genuine patient engagement in defining the problem with clinicians/academia/industry listened to
- addressing a clinical specialisation where there is a:
 - significant population with high associated morbidity;
 - high cost of delivering care across the whole health and care services
- demonstrate generic capabilities necessary for a research organisation of this type, including:
 - effective collaboration agreements with several businesses with specific interests in developments in this area, and linkages with networks by which to enlarge this (e.g. UK CRN, PASA/CEP, Medical Devices Faraday KTN, RDA, Medilink etc);
 - linkages with sufficient academic departments with specialist skills necessary to support technologies through their development processes (as defined in KTN Routemap proposal), including linkages with health economists;
 - linkages with a critical mass of clinical departments in other Trusts in similar areas of clinical specialisation with a focus on capturing and distilling existing disparate sources of expertise and knowledge;
 - the commitment of the Host Trust CEO to the long-term development of the HTC;
 - linkages with a nascent UK-based industry, as highlighted in the HITF report.
- have transparent and robust corporate governance arrangements, e.g. be a Company Limited by Guarantee.

EXAMPLE OF HTC STRUCTURE

Figure 3. Pictorial Example of an HTC Structure



Comments:

- HTC is based in a Trust which is a major provider of services within the area of specialisation of the HTC and can provide:
 - a home for HTC Director and the staff necessary to undertake the management, clinical research and specialised research with particular knowledge or skills to support development of HTC theme;
 - infrastructure to support incubator units. Starts-ups/spins-outs gain access to clinicians & clinical trial coordination;
 - support services available within the Trust.
- HTC is focussed on two main activities:
 - initiating and undertaking collaborative projects in its area of interest which may be funded from a wide range of sources (e.g. charity, research council, industry, direct government commissioned work, Trust funding);
 - dissemination and community building through promotion of seminars/workshops, both in UK and internationally; and through development of training programmes related to the theme of the HTC.
- HTC must have an inclusive culture and will realise its potential impact through developing links with other similar departments/groups – ‘HTC Nodes’. HTC Nodes will have:
 - complementary skills and activities to the HTC (including complementary health service functions – e.g. Social Services, etc);
 - access to appropriate patients and support staff;
 - capacity/skills to participate in research projects with appropriate support from the HTC.

- Involvement of industry, academic and other groups will be relatively flexible, both in the centre and the projects and dissemination programmes, and will reflect needs of specific activities.
 - industry provides funding for clinical trials at the HTC for products developed independently. HTC attracts clinical trials from international sources to be performed in the UK;
 - large companies (i.e. competitors) can collaborate at a precompetitive level through sharing knowledge on clinical needs;
 - universities collaborate with the HTC through conduct of basic research within the university and development of products through spins outs located in the HTC incubator units;
 - all parties participate with the HTC in sharing and promoting knowledge on clinical needs. HTC becomes a centre of expertise in the clinical aspects of the HTC theme.
- The HTC will have a Steering Board which can help to review strategy of the HTC and maintain its culture of openness and inclusiveness.
- The fundamental goal of the HTC is to deliver better technologies to patients: the HTC therefore needs to recognise the importance of protecting IP to ensure its effective transfer and exploitation.
- HTC will work with NHS Innovation Hubs to:
 - identify other potential HTC Nodes and collaborators throughout UK;
 - protect and transfer resulting IP.

REFERENCES

¹ “Securing our Future Health: Taking a long-term View”, accessible on HM Treasury website www.hm-treasury.gov.uk

² “Better health through partnership: a programme for action” Healthcare Industries Task Force Final report, November 2004

³ The House of Commons Health Committee HC 398-1 12 April 2005 “The use of New medical Technologies within the NHS” Volume 1