



**Research & Development
Directorate**

Annual Report

2000 - 2001

EXECUTIVE SUMMARY

The further achievements of Year 3 of the *R&D Agreement* complete the Trust's agenda to transform its management arrangements for research and development (R&D). Its track record over the past three years confirms the Trust's ability to deliver high quality research, disseminate research findings and identify and exploit Intellectual Property. During the year, Mental Health R&D funding was disinvested for transfer to the Manchester Mental Health Partnership and the five remaining R&D themes have been reviewed and consolidated. The R&D Theme Leads and the SMUHT Clinical Academic Group (CAG) Lead have worked together to focus research programmes to reflect the Trust's clinical and academic strengths.

The Trust's research portfolio:

- includes two of the national R&D priorities;
- maps to areas of clinical expertise within the Trust;
- reflects the close links which the Trust has with primary care and mental health;
- illustrates a range of research collaborations with other NHS and academic organisations;
- demonstrates an increase in research capability within the non medical professions;
- evinces the close cooperation between clinical and scientific staff.

The Trust's R&D strategy has been revised to take account of Trust achievements and new challenges. Comprehensive arrangements are in place to manage Intellectual Property generated by Trust staff. Ways to progress the agenda for involving consumers in NHS R&D have been defined. The *SMUHT Research Charter* is being revised to reflect the new standards set out in the *Research Governance Framework for Health and Social Care*.

The scope and quality of data about research projects and research outputs have been improved. 256 projects were in progress during the financial year, with 379 papers and abstracts published in scientific/health management journals and 28 contributions made to scientific/clinical reference texts during 2000. Mechanisms for peer review of own account research have been explored, with a local independent peer review board emerging as the preferred option. Collaborative working with Trusts and Universities across the North West Region, to develop management responses to NHSE priorities and policies, has been expanded and consolidated.

An overview of recent research achievements in each of the five themes has been compiled, illustrating the Trust's successes in attracting major external funding; the range of higher degree research work that Trust researchers host and support; the variety of national and international research partnerships that are in place; the contributions made by Trust researchers to the development of national and international clinical guidelines, and, the pragmatic impact of research findings on clinical practice.

New cancer research initiatives, supported by £214,505 from Trust endowments, are ongoing. Further funding (£25,000 per annum for 3 years) is being identified to support research undertaken by both novice and experienced researchers in the non medical professions. During 2000/01, £32,390 in funding was made available to support research skills training for the non medical professions. The Trust was selected for two Wellcome CRF start-up projects which are enabling the development and testing of CRF procedures and providing training to CRF research nurses.

Planning for the new Education and Research Centre, in partnership with the University of Manchester, is based on an interlinked strategic vision for education and research in the Trust. The Trust Board continues to accord the highest priority to R&D, recognising that undergraduate teaching, postgraduate medical education, audit and high quality R&D go hand in hand with high quality healthcare.

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I. INTRODUCTION

1. Background

1.1 Research in South Manchester

1.1.1 South Manchester University Hospitals NHS Trust (SMUHT) undertakes and reports high quality research which addresses national R&D priorities and attracts international recognition. The Trust's research programmes reflect the synergies of both established and developing research partnerships between clinical specialties in the Trust, the Universities of Greater Manchester and other health care, academic and industrial organisational partners in the UK, Europe and world-wide.

1.1.2 A substantial element of the Trust's research portfolio links across the clinical interface into primary care. The R&D Directorate is working closely with South Manchester Primary Care Trust (SMPCT) to develop complementary R&D strategies and to provide operational support to PCT officers and primary care research teams.

1.1.3 The appointment of a Clinical Academic Group (CAG) Lead for SMUHT, by the Faculty of Medicine, has formalised the University of Manchester's commitment to the academic and research strengths of the Trust. This renewal is further reflected in a range of partnership initiatives in which the two organisations are engaged.

1.1.4 The Trust has consolidated its working links with all the Universities of Greater Manchester and the teaching Trusts across the Region, laying the foundations for the development of research consortia and joint research strategies.

1.1.5 Year 3 of the R&D Agreement has seen:

- completion of Year 3 objectives set out in the R&D Strategy;
- disinvestment of Mental Health R&D funding for transfer to the Manchester Mental Health Partnership (MMHP);
- comprehensive review and description of the major research foci and strategic direction of each R&D theme;
- a range of initiatives to address local, regional and national R&D priorities.

1.1.6 The R&D Directorate continues to make significant contributions to the business of the Trust through membership on standing committees and the Trust Board; development of management responses to NHSE policy; provision of operational support to researchers and organisational partners, and, ongoing review and rationalisation of the Trust's research portfolio to align it more closely with the Trust's areas of clinical excellence.

II. PROGRESS AGAINST STRATEGIC PLAN

2. Strategic Framework

2.1 Trust Board Commitment

2.1.1 The Trust Board has endorsed R&D as a core activity of the Trust and fully supports the R&D Directorate's R&D strategy for the Trust.

2.1.2 The continuing commitment of the Chief Executive and Director of Finance is evidenced by monthly progress meetings with the Director of R&D and R&D Manager. These meetings enable an exploration of R&D strategic issues, discussion of complex problems and agreement of action plans.

2.1.3 The Chairman and Medical Director receive copies of R&D Committee minutes and, where appropriate, reflect the business of the Committee in other Trust fora. The Medical Director, as Chair of the Commissioning Group for the new Education & Research Centre, is leading the development of an inter-linked strategic vision for education and research in the Trust. The Chairman has given particular support to the development of R&D capability, consumer involvement in R&D, and management arrangements for Intellectual Property. He has led the investment of Trust endowment funds in a major programme of cancer research and in a new initiative to fund research undertaken by both experienced and novice researchers within the non medical professions.

2.2 Challenges

2.2.1 Against this background, during 2000/01, the introduction of a *Research Governance Framework* and the announcement of new *Support for Science* and *Priorities & Needs* R&D funding arrangements have given an impetus to ongoing efforts to focus and rationalise Trust research programmes; to review the Trust's R&D income, and, to assess the impact of research outputs on national R&D priorities and clinical service provision. The R&D Directorate has responded to these challenges with successful engagement of the Trust's research community to provide timely and comprehensive responses to consultation documents and detailed information returns to support the development of new R&D financial frameworks and strategic reviews of R&D priorities.

2.3 R&D Strategy

2.3.1 The Trust's R&D strategy sets out an action plan of year-on-year objectives and demonstrates short-term and long-term R&D goals to take account of local, regional and national R&D priorities. The strategy incorporates an R&D mission statement which augments the SMUHT mission statement and summarises key elements of the Trust's R&D philosophy. Strategic objectives for Year 4 have been defined which incorporate new requirements set out in the *2001 Variation to the R&D Agreement (Appendix 1)*.

2.3.2 The primary aim of the strategy is to ensure that high quality peer-reviewed research is conducted which addresses national R&D priorities, reflects the clinical expertise within the Trust and meets Regional Office, Health Authority and Trust objectives. The strategy addresses the requirement to manage R&D, research governance and Intellectual Property generated by Trust staff and to involve consumers in R&D.

2.3.3 Objectives for Years 1 to 3 are set out in the R&D strategy under six headings. These are listed below, together with the sections of this report which detail Year 3 achievements:

- Management (Part III, Section 13, Section 21);
- Finance (Section 9, Part V, Section 18);
- Governance (Section 3, Section 19);
- Capability Building (Section 7, Section 8, Section 20, Section 22);
- Partnerships (Section 6, Section 7, Section 10);
- Intellectual Property (Part VII).

A new heading, *Consumers in R&D*, has been added for Year 4 objectives.

2.3.4 All performance indicators were achieved against Year 3 strategic objectives with three exceptions. R&D budgets are not yet considered separately by Clinical Divisions in their annual business planning; procedures to move support costs between R&D themes are still virtual; implementation of the SMUHT *Research Charter* has been delayed pending publication of the *Research Governance Framework*.

2.4 R&D Business Plan

2.4.1 A detailed R&D business agenda for the period of the *R&D Agreement* is set out in the R&D strategy. A summary of 2000/01 business achievements is provided in **Appendix 2** and details are given in the relevant sections of this report.

3. Quality

3.1 Governance

3.1.1 The R&D Committee has responsibility for putting in place and administering a research governance framework.

3.1.2 The annual *Researchers' Meeting with the Chief Executive* in October 2000 included a presentation by the R&D Manager on the *Draft Research Governance Framework for Health and Social Care*. This was followed by an *R&D Briefing Note* which was circulated in November 2000 to all research staff in the Trust.

3.1.3 In November 2000, the R&D Manager presented a paper to the Trust's Clinical Governance & Quality Committee outlining the organisational requirements of the *Draft Research Governance Framework* and the Trust's response to the national consultation (**Appendix 3**).

3.1.4 The Deputy Director of R&D has taken a national lead on pharmacy aspects of clinical trials, with presentations at national meetings about management of NHS R&D, the role of LRECs/MRECs and research governance. SMUHT Pharmacy has been awarded the *GHP Hospital Pharmacy Effectiveness Award* by the NHSE North West Medicines Management Team.

3.1.5 The R&D Manager was invited to give a presentation to the *Brunswick Group* of University Administrative Heads of R&D, outlining the implications of the *Research Governance Framework* for universities.

3.2 Research Charter

3.2.1 In February 2000, the R&D Committee adopted a *Research Charter*, prepared in consultation with South Manchester LREC, which set out a research governance framework for the Trust. The charter covered:

- *Good Clinical Practice* in research;
- research involving human tissue or genetic material obtained surgically;
- notification of serious adverse events;
- ethical and scientific standards;

- complaints;
- research misconduct;
- research monitoring.

3.2.2 The R&D Committee also adopted an *Investigator Agreement for the Conduct of Research*. Researchers will be required to sign this agreement confirming their compliance with the SMUHT *Research Charter*.

3.2.3 In light of the detailed requirements set out in draft *Research Governance Framework*, the R&D Committee delayed implementation of the *Research Charter* until the definitive guidance was published. The charter is now being modified to reflect all the standards set out in the *Framework*

3.3 *Good Clinical Practice (GCP)* in Research

3.3.1 The achievement of *GCP* in the designing, conducting, recording and reporting of research in the Trust was endorsed as a strategic aim in February 2000 by the R&D Committee. To this end, the Committee has adopted the ICH *GCP* (1997) guidelines as the future standard for researchers in the Trust.

3.3.2 The SMUHT R&D Directorate and Department of Clinical Audit, together with SMPCT, MMHP and the Medicines Evaluation Unit (an independent company which exists to generate funds for NHS medical research), collaborated on two bids for funding to develop an innovative *GCP in Research* training programme for the NHS. The project aims were:

- to link the evaluation of facilities, written procedures and record keeping of selected research teams (obtained through formal audit) to the *GCP* training of research staff in all disciplines;
- to develop exemplar training procedures for developing ownership by researchers of the attainment and maintenance of *GCP* standards;
- to develop mechanisms to utilise staff trained in *GCP* as trainers in a continuous, rolling *GCP* training programme within partner organisations and, if required, within the North West Region;
- to disseminate exemplar *GCP* training methods across the NHS and to promote their implementation.

Bids for Supra District Audit and Education & Training Consortium funding were submitted but were considered to be outside the remits of these organisations.

3.4 Project Approval Procedures

3.4.1 All research projects undertaken in the Trust must comply with the procedures for research notifications, approvals, indemnifications and contracts, set out in *R&D Project Approval in SMUHT: A Researcher's Guide*. Researchers are required to provide copies of grant applications, research protocols, and, where applicable, LREC/MREC application form(s) (including copies of all patient information documents) and approval letter(s) for R&D Directorate files.

3.4.2 *ABPI Indemnity* forms are signed by the Chief Executive. The signatory for research contracts depends on the value of the contract: < £50,000 R&D Manager; < £150,000

Director of R&D; < £500,000 Director of Finance; ≥ £500,000 Trust Board. All indemnity forms and contracts are held by the R&D Directorate on behalf of the Trust.

- 3.4.3 From January 2001, it has been obligatory for researchers to provide evidence that commercially contracted research benefits the Trust, in order to obtain management approval.

3.5 Quality Assurance

- 3.5.1 Research funded within the *Mutual Obligation Arrangements* in HSG(97)32 is not submitted to local peer review.

- 3.5.2 Currently, other projects (ie those sponsored by charitable or commercial organisations and own account) are assessed by the Director of R&D and Theme Leads on the basis of *NRR* records. This is primarily an assessment of their fit within the R&D themes and does not include a specialist view.

- 3.5.3 In October 2000, the Chief Executive and the Director of R&D undertook a formal consultation with researchers about three options for a local peer review process:

- drawing on a regional list of reviewers;
- using the Trust's R&D Theme Leads plus external reviewers;
- setting up an independent review board.

The consensus was an independent review board.

- 3.5.4 The R&D Committee has agreed the constitution of a SMUHT Peer Review Committee which will meet monthly to peer review research outside the *Mutual Obligation Arrangements*. The committee will include the Director of R&D, the CAG Lead and external reviewers who are senior researchers representing Medicine, Surgery, Public Health, General Practice, Nursing and Professions Allied to Medicine.

- 3.5.5 The R&D Committee, in recognition that timely peer review is essential, endorsed a revised project approval process (**Appendix 4**) in October 2000. The process now incorporates peer review which will be undertaken in parallel with ethical review by LRECs/MRECs.

- 3.5.6 In February 2001, the R&D Committee gave notice to the Endowment Committee of its intention to introduce peer review of research projects funded by endowments held in the Trust. A change in the application procedure for access to endowment funds by account holders has been approved by the Director of Finance. Applicants will, in future, need to provide evidence of R&D management approval before the Endowment Committee can approve the release of the requested funding.

- 3.5.7 SMUHT is collaborating in a *North Western Regional Register of Reviewers for Own Account and Local Charity Funded Research*. 40 researchers based in the Trust, representing SMUHT and MMHP, have agreed to join the register and act as reviewers on a reciprocal basis.

4. Ethics

4.1 Measures to Support Ethics Agenda

- 4.1.1 The Deputy Director of R&D is a member of South Manchester Local Research Ethics Committee (LREC) and the Director of R&D is a member of the Manchester Multi Centre Research Ethics Committee (MREC).
- 4.1.2 The R&D Information Officer provides advice and guidance to researchers about requirements for ethical approval and administers effective information flows between the R&D Directorate and South Manchester LREC.
- 4.1.3 Ethical approval of SMUHT research projects is given by South Manchester LREC on the understanding that the project is given R&D management approval by the Trust.
- 4.1.4 During the year, the R&D Manager worked closely with the South Manchester LREC Manager in developing SMUHT's responses to research governance requirements (see Section 3.2.1).

5. Relevance, Impact and Importance

5.1 National

- 5.1.1 Two of the Trust's R&D themes reflect national priority areas for health gain and R&D: cancer and palliative care; coronary heart disease (CHD) and stroke. These two themes represent 42% of the Trust's current research projects. There is also major research activity related to other national priorities; for example, 18% of the Trust's research projects link to primary care.

5.2 Regional

- 5.2.1 The Trust's R&D strategy includes objectives which contribute to the achievement of the four R&D objectives set out in the NHS Executive North West 1999/2002 Business Plan.

5.3 Local

- 5.3.1 Relevance of the Trust's research programmes to Manchester Health Authority's priorities for action in its 2000/01 *Health Improvement Programme (HimP)* can also be demonstrated. The priorities for action in the *HimP* for 2000/01 are given below, with examples of SMUHT research areas which relate to these priorities.

Priorities	Research Areas
Children/Young People	asthma and allergy; community epidemiology.
Priorities	Research Areas
Older People	needs of relatives and carers; interventions in nursing homes; palliative care; chronic wounds,

	ulceration and pressure sores.
Coronary Heart Disease/Stroke	heart failure; coronary syndromes; stroke; vascular surgery; cardiac lesions in ankylosing spondylitis.
Health Inequalities/ Social Exclusion	community epidemiology; medicines information needs; neurologically disabled adults; wheelchair users; risk factors in respiratory disease; occupational asthma.

5.3.2 The Trust's research programmes also reflect SMPCT's focus areas for health improvement. Those of particular relevance are:

- improving the health and well-being of older people;
- coronary heart disease;
- local action on childhood asthma.

5.3.3 SMPCT is R&D Lead for North and Central Primary Care Trusts. The close working of SMUHT and SMPCT to develop complementary strategic perspectives for R&D ensures, therefore, that SMUHT obtains a pan-Manchester view of R&D issues in primary care.

5.3.4 *Working for Health in Wythenshawe*, which is one of SMPCT's partners in actioning health gain targets set by Manchester Health Authority, is also working with the SMUHT R&D Directorate in actioning the agenda for consumer involvement in NHS R&D.

6. Primary Care

6.1 Research Activity Involving Primary Care

6.1.1 A significant number of the research projects within the Trust have one or more of the following links with primary care:

- at least one research investigator is a primary care professional;
- patient recruitment and data collection take place within primary care;
- the research topic relates specifically to the activities of primary care professionals.

6.1.2 18% of the Trust's research work in 2000/01 linked across the clinical interface with primary care. This activity formed a proportion of R&D theme activities as follows: *Cancer* (9%); *Cardiovascular Disease* (11%); *Developing Fields* (27%); *Physiological Studies* (22%); *Respiratory Disease* (22%).

Examples of primary care-linked research projects were:

- the cost of respiratory illness to primary care;
- feasibility of measuring health status using the EuroQol EQ-5D questionnaire;

- use of ACE inhibitors and angiotension II antagonists to treat hypertension in primary care;
- health economics of web-based medicines formulary and treatment guidelines in GP practices;
- patient compliance in the treatment of leg ulcers or skin grafts;
- impact of respiratory symptoms in adults in primary and secondary care workloads;
- indoor pollutants as environmental factors in the aetiology of asthma;
- economic impact of high-technology home therapy in cystic fibrosis;
- primary prevention of asthma by allergen avoidance in high risk infants;
- low back pain trial in primary care.

6.1.3 The 2000/01 investment of R&D support funding in primary care research in each of the five research activity areas is detailed in Table 2 (**Appendix 5**).

6.2 Primary Care Research in South Manchester (PRiSM) Network

6.2.1 SMUHT is a collaborative partner in the PRiSM network. Trust researchers are available for advice and assistance in developing links with hospital and university researchers and the R&D Directorate staff provide operational support to the primary care members of the network.

6.2.2 SMUHT has taken on the role of convenor of PRiSM from Manchester Health Authority. The R&D Manager has initiated a series of meetings of PRiSM members with representatives of NHSE North West and SMPCT to explore future options for the PRiSM partnership. The R&D Directorate also provides an information service to PRiSM members to ensure their awareness of new national R&D policies and relevant funding opportunities.

6.2.3 Collaborative research in respiratory disease at the North West Lung Centre (NWLC) is well established with one of the PRiSM member general practices, Bowland Road Medical Centre. The NWLC Charity continues to fund elements of this research as well as studies undertaken within the GP Research Unit based at Wythenshawe Hospital.

6.3 Working Links with South Manchester Primary Care Trust (SMPCT)

6.3.1 The SMUHT Director of R&D and R&D Manager have established strong working links with SMPCT and are providing support to the R&D scoping exercise being undertaken by the SMPCT Chair of CRED. Areas for collaboration with SMUHT, identified by the SMPCT Chief Executive, include funding opportunities, staff training and leadership/strategic steer for R&D in the PCT. The SMPCT Chief Executive invited input from the SMUHT R&D Manager for a paper, *R&D in Manchester PCTs – April 2001 Onwards*, presented to the SMPCT R&D Strategy Group in March 2001.

6.3.2 SMUHT and SMPCT have worked collaboratively to develop local responses to national agendas for consumers in NHS R&D, *Good Clinical Practice* and R&D capability building in primary care.

6.4 Withington Community Hospital Development

6.4.1 SMUHT researchers with community-based research programmes within South Manchester support the concept of the community hospital serving as a base for primary care and community-based research. This facility offers the potential to accommodate peripatetic researchers from University or NHS partner organisations - whose research would be most appropriately conducted from a community base as opposed to an acute hospital base. The R&D Manager has strongly promoted the need to include electronic information sources for users of the community hospital.

7. Partnerships

7.1 Regional, National and International Partnerships

7.1.1 Trust researchers are involved in a wide range of pan-Manchester, regional, national and international research partnerships. Details are given in the R&D theme summaries (**Appendix 6**).

7.1.2 Researchers are also involved in partnerships which have contributed to the development of national and international clinical guidelines. Examples can be found in the R&D theme summaries (**Appendix 6**).

7.1.3 Details of national, European and international research collaborations, which are provided in the R&D theme summaries (**Appendix 6**), demonstrate the range of institutions world-wide which link into research programmes in the Trust.

7.2 Universities of Greater Manchester

7.2.1 The Trust has engaged in a wide range of initiatives with the Universities during the course of the year. These initiatives have laid the foundations for NHS/ academic groupings to bid for *Priorities & Needs* funding.

7.2.2 The Trust has endorsed the establishment of the Institute of Health Sciences which aims to bring together the major groups engaged in health sciences research in the University of Manchester and to work in partnership with local NHS organisations. The Institute offers potential to promote research synergies within and between partner organisations and maximise opportunities for collaborative research programmes. Through representation on the Institute's Board, the Trust will be seeking to strengthen links into the basic science research programmes at the University.

7.2.3 The appointment of a Clinical Academic Group (CAG) Lead for SMUHT within the Faculty of Medicine has formalised the University of Manchester's commitment to building on the academic, research and clinical strengths of the Trust. As part of the clinical reorganisation of the Trust to a single site, the CAG Lead is undertaking a major review of the Trust's University links which is endorsed by the Trust Board.

7.2.4 The CAG Lead has overall responsibility for delivering the University agenda in South Manchester, ensuring that:

- academic staff deliver as teaching leads;

- the research agenda prospers and reflects agreed strategic objectives of the Faculty of Medicine;
 - basic science research collaborations with the University are supported and extended;
 - research programmes reflect the Trust's clinical and academic strengths;
 - the Trust is appropriately positioned within the review and reorganisation of the Faculty of Medicine's Research Divisions;
 - academic interests are reflected within the work of the Trust's R&D Committee.
- 7.2.5 The R&D Manager and the Head of the University of Manchester Research & Graduate Support Unit (RGSU) work together to ensure that NHSE/HEFCE policies and issues are addressed by their organisations' R&D management arrangements. The R&D Manager has been invited to contribute to a two-day meeting of the *Brunswick Group* of University Administrative Heads of R&D with a presentation on the implications of the *Research Governance Framework* for universities.
- 7.2.6 The R&D Manager also meets regularly with the Faculty Research Administrator (Medical School) to discuss matters of mutual interest and to strengthen SMUHT's research profile within the Faculty. They have cooperated closely in the exchange and compilation of information for the next HEFCE *Research Assessment Exercise*. The Director of R&D provides regular updates on NHSE R&D policy issues to the Faculty of Medicine's Research Board.
- 7.2.7 During the year, the R&D Manager explored with the Dean of the University of Manchester School of Nursing, Midwifery and Health Visiting, mechanisms for mutual support. As a result, the R&D Manager was invited to become a member of the School's R&D Committee. Its bi-monthly meetings have a standing agenda item, *NHS Update*, to enable the R&D Manager to develop the Committee's understanding of Department of Health policies and issues and their impact on University research activities. As well, academic staff within the School have been identified to advise Trust researchers in the non medical professions on research methodology - particularly, qualitative research and action research. In March 2001, the R&D Manager arranged a seminar for the monthly *School External Seminar Programme* on the topic, "Submitting a Research Grant Application". The R&D Directorate now routinely includes the School in its electronic notifications of national R&D programmes and other relevant funding opportunities.
- 7.2.8 During the year, the Chief Executive explored with the Director and Deputy Director of R&D, the CAG Lead, and the R&D Manager, mechanisms for linking with the Universities of Manchester and Salford to provide research support to Trust researchers in the non medical professions who are beyond novice level. The SMUHT team developed a proposal for a jointly-funded multidisciplinary research unit comprising a Clinical Chair, a Senior Lecturer and Research Fellow - ideally, with each representing a different healthcare profession. The benefits of the unit were identified as:
- contributing to an environment at SMUHT which encourages retention of non medical researchers beyond novice level;
 - serving as a platform for Masters-level and doctoral studies;

- expanding University programmes of research in one of the Trust's R&D themes of *Cancer*, *Cardiovascular Disease* or *Respiratory Disease*, including community epidemiology;
- developing research and clinical links with Primary Care Trusts;
- contributing to the development of an NHS/academic research grouping eligible to bid for NHS *Priorities & Needs* funding;
- attracting new external research grants which can be returned for the HEFCE *Research Assessment Exercise* and for NHS *Support for Science*.

7.2.9 This model for collaborative working was subsequently explored with the Dean and the Associate Dean (Research) of the Faculty of Health and Social Care, University of Salford. Both organisations endorsed its principles but acknowledged that further discussion would need to await completion of the transition to a single site Trust.

7.2.10 The SMUHT R&D Manager and the Research Development Manager in the Faculty of Health and Social Care were given the brief by their organisations:

- to exchange organisational research policy documents (see **Appendix 7**);
- to explore support mechanisms for non medical researchers;
- to explore potential research synergies.

7.2.11 A mechanism to fast track methodology queries from Trust researchers in the non medical professions to the Research Development Manager was agreed. This arrangement is being monitored to assess its benefits to both organisations.

7.3 Trusts within the North West Region

7.3.1 SMUHT, SMPCT and the Medicines Evaluation Unit collaborated in the development of a *GCP* project which incorporated audit of 10 research areas; development of an exemplar *GCP* training programme, and, dissemination of *GCP* training methods across the wider NHS. This was a local response to the Department of Health *Guidelines for Good Clinical Practice and Clinical Trials* and illustrates the type of innovative collaborations which the SMUHT R&D Directorate has succeeded in establishing.

7.3.2 The R&D Directorate enjoys close working relationships with the R&D Directorates at Central Manchester Healthcare, Christie Hospital, Salford Royal Hospitals and Manchester Children's Hospitals NHS Trusts, as well as Royal Liverpool and Broadgreen University Hospitals, The Royal Liverpool Children's Hospital and Aintree University Hospitals NHS Trusts. These links enable collective problem-solving; joint development of management solutions to national R&D policies, and, directives and the sharing of best practice.

7.3.3 SMUHT and Christie Hospital NHS Trust work closely in the delivery of a range of cancer services and in collaborative research programmes. In advance of the formal establishment of the Greater Manchester & Cheshire R&D Network, the SMUHT Director of R&D has initiated discussions with the Chair of the Greater Manchester & Cheshire Cancer Services Network to explore ways that the two Trusts can build on existing relationships to increase working across organisational networks. The R&D Directorate staff have worked closely with the Christie Hospital NHS Trust to

identify inter-Trust research working and to make pro rata allocations of external R&D funding to reflect each Trust's contributions to joint research projects.

- 7.3.4 The Trust's R&D strategy calls for the R&D Directorate to assist with the building of R&D capability on a pan-regional bases. The R&D Manager, in conjunction with the R&D Manager from Central Manchester Healthcare NHS Trust, runs the North West R&D Managers' Forum which meets bi-monthly to build understanding of the national agenda for R&D. The R&D Directorate undertakes the administration of the bi-monthly meetings of the regional forum. The R&D Manager is an early point of contact for R&D Managers/Coordinators in the region for advice and support.
- 7.3.5 The SMUHT R&D Manager arranged and chaired the March 2001 *Away Day on Research Governance* for Forum members. Attendees also included representatives from all the Universities in the North West, as well as PCTs, Public Health and PRiSM.
- 7.3.6 The R&D Directorate has made available exemplar policies, procedures and pro formas to R&D Directorates across the North West Region to assist them in putting in place management arrangements for the notification and approval of research, peer review of research, indemnification of research and management of Intellectual Property.
- 7.4 Community Health Council (CHC)
 - 7.4.1 The collaborative work with South Manchester CHC is described in Section 23.
- 7.5 Manchester Intellectual Property (manIP) Consortium
 - 7.5.1 The R&D Manager, as Secretary of the manIP Management Group, undertakes a substantial liaison role with the eight other partners - University of Manchester, University of Salford, UMIST, Manchester Metropolitan University, Central Manchester Healthcare NHS Trust, Salford Royal Hospitals NHS Trust, Manchester Children's Hospitals NHS Trust and Lyndon Davies Associates.
 - 7.5.2 Expansion of University research links has been prompted by the manIP technology audits which have identified common areas of research work. These have served as catalysts to initiate inter-institution collaborations in the further development of research innovations and to explore ways to group Intellectual Property for assessment of commercial potential. (Further details are provided in Part VII.)
- 7.6 Wellcome Clinical Research Facility (CRF)
 - 7.6.1 The R&D Manager and the SMUHT Assistant Director of Finance (R&D), on behalf of the CRF consortium partners, worked with the CRF Administrator to re-base the CRF business plan to reflect available funding. The R&D Manager produced a paper setting out funding issues for consideration by the CRF Management Committee (**Appendix 8**) and worked with Trust partners and NHSE North West to develop a successful bid for an additional allocation of £591k *Budget 2* funding for 2001/02 costs to the NHS of hosting research in the CRF.
 - 7.6.2 Two SMUHT research teams were selected for start-up projects for the CRF:

- The IFWIN Study to investigate the effects of early intervention with low dose inhaled corticosteroids (A Woodcock, A Custovic and S Langley);
- Cerebral emboli and venous-to-arterial circulation shunts in dementia (A Burns, C McCollum, A Jackson, G Dunn and G Macfarlane).

The latter project is a collaboration between SMUHT and MMHP. Both projects have been assigned a CRF Research Nurse for six months to enable the piloting of CRF procedures.

8. Appropriate Disciplinary Mix

8.1 R&D Support to the Non Medical Professions

8.1.1 The R&D Directorate undertakes to support non medical researchers within SMUHT as follows:

- to assist in the development of research, in particular:
 - developing research questions;
 - developing research protocols;
 - preparing grant applications;
 - preparing papers for publication or conference presentation;
 - accessing statistical support;
 - advising on LREC/MREC approval procedures.
- to provide advice to non medical researchers on the availability of research methodology courses and sources of research funding.
- to help identify appropriate research mentors (internal or external) for novice researchers.
- to include research projects, where the lead investigator is a non medical researcher, within the monitoring and review procedures for R&D Themes.
- to support the dissemination of research findings and development of research awareness and evidence-based practice through the staging of the annual conference for the non medical professions.

8.2 R&D Mentoring

8.2.1 The R&D Manager (who is an experienced researcher with extensive experience at national level in teaching research skills) takes responsibility for providing advice and support to novice researchers in the non medical professions.

8.2.2 The R&D Directorate dealt, on average, with 5 requests per week for assistance with:

- identifying appropriate sources of external funding;
- developing research questions;
- writing research proposals;
- preparing applications for training bursaries/grants;
- preparing abstracts/poster presentations;

8.2.3 The support that has been put in place in the course of the year, for non medical staff seeking to move from own account research to externally funded work, is detailed in Sections 7.2.7 to 7.2.11.

8.3 Access to the Knowledge Base: Library and IT Facilities

8.3.1 In recognition that further improvements in access to the knowledge base require inter-departmental cooperation, the R&D Manager and the Head of IM&T have established a forum of IT, education, library and R&D support staff. The forum's remit is to develop a joint Trust/University IM&T strategy and a single approach to IM&T infrastructure across the Trust.

8.4 Educational Programmes to Support R&D Capability Building

8.4.1 During the year, the in-house programme of R&D capability building for the non medical progressions continued under the aegis of the Department of Medical Statistics (see Section 11.4)

8.5 Dissemination of R&D Information

8.5.1 The R&D Information Officer undertook R&D awareness-building for the non medical professions through:

- maintaining a database of all specialist, research and education staff in the non medical professions who have a research remit within their role;
- circulating calls for grant applications;
- searching web sites for funding sources relevant to researchers' research fields;
- circulating R&D-related information.

8.5.2 The *SMUHT 3rd Annual R&D Conference for Nurses, Midwives and PAMS* was held in April 2000. The programme, which included 16 papers and 40 posters, demonstrated continued improvement in the science of the projects that were reported. Nonetheless, many of the submitted abstracts and posters did not satisfy all the standard peer review criteria. The organising committee decided in future, therefore, to submit conference abstracts to formal peer review and to assist presenters in revising their abstracts to meet accepted standards for scientific content. As in 1999, the event was well attended by staff from neighbouring acute and community trusts.

9. Cost

9.1 Changes in Research Activity

9.1.1 R&D support expenditure in 2000/01 and indicative expenditure for 2001/02 (see Part V) reflect on-going changes in research activity.

9.2 Review of R&D Support Costs

9.2.1 In 2000/01, the Assistant Director of Finance (R&D) and the R&D Manager continued work on a costing model, with the aim of producing R&D expenditure plans to link into the business planning cycle of Clinical Divisions.

9.3 Recovery of Full Costs of Commercial Research

9.3.1 Processes for agreeing the costs of commercial research and for re-investing commercial income in R&D activity have been fully implemented during 2000/01 (see Sections 3.4.1 to 3.4.3).

10. Integration with Other NHS Activities

10.1 Local Patient Care Services

10.1.1 The R&D themes reflect the Trust's areas of clinical excellence and promote research programmes which are consistent with the Trust's service profile. Research programmes also reflect established service links with primary and community care (eg *Developing Fields* and *Respiratory Disease*) and with other NHS Trusts (eg *Cancer* and *Cardiovascular Disease*).

10.1.2 Research collaborations, within clinical services based in South Manchester, are continuing between SMUHT and MMHP. Examples include:

- Old Age Psychiatry and the Vascular Studies Unit are conducting a pioneering investigation of venous-to-arterial shunts and cerebral microemboli in Alzheimer's disease and vascular dementia;
- Clinical Psychology is collaborating with the Renal Dialysis Unit in an investigation of dialysis patients' adherence to fluid restrictions and the role of their treatment beliefs and illness perceptions. The prevalence of psychological distress - in particular, clinically significant depression and anxiety - is also being examined in this patient group;
- Old Age Psychiatry has been working with Respiratory Medicine to investigate depression and anxiety in elderly patients with COPD;
- Adult Psychiatry has worked with Pulmonary Oncology in randomised trials of drug therapies versus best supportive care, with Quality of Life as the primary outcome;
- Adult Psychiatry has worked with Breast Surgical Oncology to look at mental health and body image outcomes after bilateral 'risk reducing' mastectomy in women at high risk of breast cancer;
- Clinical Psychology is working with the Burns and Reconstructive Surgery Unit to examine the prevalence of post traumatic stress disorder (PTSD) and psychological morbidity in burns patients.

10.1.3 An innovative project is being undertaken by the SMUHT Pharmacy, in partnership with SMPCT, to investigate the health economics of a web-based medicines formulary and treatment guidelines. This follows a collaborative project to review the management of repeat prescribing in primary care.

10.2 National R&D Priorities

10.2.1 Two of the R&D themes, *Cancer* and *Cardiovascular Disease*, reflect national priorities for *R&D Levy* funding (Section 5). The Trust's research programmes demonstrate significant success in bids for regional and national *Budget 2* funding (Part V). Links with primary care are detailed in Section 6.

10.3 Community Health Council (CHC)

10.3.1 The collaborative work with South Manchester CHC is described in Section 23.

10.4 Education and Training

10.4.1 The R&D Manager is a member of the Trust's Education and Research Centre Commissioning Group and the Education Committee.

10.5 Clinical Audit

10.5.1 The Clinical Audit Manager is an observer at R&D Committee meetings and the R&D Manager is a member of the Clinical Audit Committee, providing the opportunity for the regular exchange of information and ideas.

10.5.2 Nursing and midwifery Audit Leads are designated within clinical divisions to promote the development of nursing and midwifery audit and to identify research issues from audit results.

10.5.3 The R&D Directorate and the Department of Clinical Audit are working together on involving consumers in research (see Section 23).

III R&D MANAGEMENT

10.6 Infrastructure

11.1 R&D Directorate

11.1.1 The R&D Directorate establishment is given in **Appendix 9**. Figure 1 illustrates reporting relationships for R&D within the Trust.

11.1.2 The remit of the R&D Directorate is:

Development of strategy, infrastructure and operational arrangements to manage research and development in accordance with the Trust's R&D Agreement with the Secretary of State through the NHSE North West.

Appendix 9 sets out the functions which the Directorate fulfils.

11.2 R&D Committee

11.2.1 The R&D Committee is a standing committee of the SMUHT Trust Board. The committee's membership (see **Appendix 9**), which includes the Chief Executive and Director of Finance, ensures that the Committee's discussions are informed by input from senior Trust officers and that decisions and actions link appropriately to other Trust fora. The inclusion of the CAG Lead on the Committee this year has helped the Committee to support the developing academic-research synergies between the University and the Trust. The terms of reference of the R&D Committee are given in **Appendix 9**.

11.2.2 A formal record of the meetings of the R&D Committee is prepared by the R&D Manager. (See **Appendix 10** for minutes of meetings held in 2000/01.)

11.2.3 The R&D Committee has both strategic and operational roles, providing a lead to the Trust in defining the principles which underpin the Trust's R&D activities. The R&D mission statement, adopted in February 2000, encapsulates these principles (**Appendix 1**).

11.3 R&D Theme Leads

11.3.1 The R&D Theme Leads' terms of reference are given in **Appendix 9**. The CAG Lead now contributes to their work of developing R&D strategy, focusing the Trust's research programmes and promulgating the mission of the R&D Directorate.

11.4 Statistical Support

11.4.1 The Department of Medical Statistics is responsible for:

- provision of a statistical advisory service to all Trust researchers undertaking R&D Directorate-approved projects;
- establishment of an Open Access Statistics Clinic to enable rapid access to statistical support;
- inclusion of researchers in the non medical professions in the customer base for the statistical support service;
- provision of a rolling statistics education programme open to all researchers;
- increasing collaborations in major non commercial externally funded projects.

11.4.2 During the year, monthly training half-days were delivered by the SMUHT statisticians covering:

- study design (protocol, sample size, randomisation);
- simple statistical analyses (descriptive statistics, comparative tests, confidence intervals);
- practical guide to the use of *SPSS*;
- presentation of results for publication;
- critical appraisal of research papers.

11.4.3 Open Access Statistics Clinics are held weekly at Wythenshawe Hospital (Wednesday mornings) and Withington Hospital (Friday mornings). These are heavily used by both experienced and novice researchers.

12. Information and Communication

12.1 Information Management

12.1.1 The mechanisms for management approval of research are outlined in Sections 3.4.1 to 3.4.3. Peer review processes are outlined in Sections 3.5.1 to 3.5.7.

12.1.2 The R&D Manager checks commercial indemnity agreements prior to signature by the Chief Executive and commercial and non commercial contracts prior to signature by the Director of R&D, Director of Finance and the Trust Board.

12.1.3 The R&D Administrator works closely with the University and Trust IT support staff and with the librarians on both sites to ensure that Trust *Intranet* and *Internet* links are fully utilised to support the work of the R&D Directorate. The R&D Manager is a member of the Trust's IM&T Steering Group.

12.2 Communication with Trust Researchers

- 12.2.1 The R&D Directorate has an R&D web page on the SMUHT web site (www.smuht.man.ac.uk/rd). The web page includes electronic versions of R&D Directorate policies and forms; LREC and Wellcome CRF guidance and applications; R&D Directorate notices; selected funding applications.
- 12.2.2 The R&D Administrator has been trained in web page management to enable in-house updating of the R&D web pages and expansion of web-based services including signposting to other relevant web sites.
- 12.2.3 The Trust's quarterly publication for staff, *Trust Talk*, has regular features on R&D compiled by the R&D Directorate staff. The monthly *Staff News* is also used to give R&D updates to staff. Occasional *R&D Briefing Notes* enable the Directorate to circulate a digest of information and requests for researchers' action. R&D Directorate boxes for reference copies of documents relating to the work of the Directorate as well as R&D notice boards are provided in both libraries.
- 12.2.4 The Chief Executive holds an annual *Researchers' Meeting with the Chief Executive* to provide a forum for discussion and debate between researchers and the Chief Executive (supported by the Director of Finance, the Director of R&D, Deputy Director of R&D and the R&D Manager). The purpose of these meetings is to address complex issues and undertake consultations with researchers.

12.3 Other Initiatives

- 12.3.1 Other information management responses are described elsewhere in this report:
- Sharing Information with Partners (Section 7.2, Section 7.3);
 - Research Outputs (Section 19, Part VIII);
 - Involving Consumers in NHS Research (Section 23);
 - Documenting/Protecting Intellectual Property (Section 24).

IV PROGRESS IN ACTIVITY AREAS

13. R&D Themes

13.1 Reduction of R&D Themes

- 13.1.1 The creation of Manchester Mental Health Partnership reduced SMUHT's activity areas to five R&D Themes. The research areas within each theme are listed in **Appendix 6**.

13.2 New Reporting Requirements

- 13.2.1 In September 2000, the R&D Committee expanded the research details/outcomes that researchers are required to report annually. Details of higher degrees awarded to members of research team, developments in clinical practice arising from research, Intellectual Property, memberships in major national/ international working groups and committees, and, involvement of consumers are now collected.

13.3 R&D Theme Summaries

13.3.1 Theme summaries (**Appendix 6**) articulate the major research foci and strategic direction of the themes during 2000/01. The summaries provide a global view of the research activity in each theme, outline recent significant research achievements and demonstrate the pragmatic impact of research on clinical service provision.

13.4 Allocation and Expenditure of Support Costs

13.4.1 The R&D theme summaries outline current research and give examples of major collaborations. Details of indicative and actual spend of support costs in each area are given in Part V.

V FINANCIAL INFORMATION AND TABLES

14. Funding

14.1 External Funding (*Mutual Obligations*)

14.1.1 For 2000/01, the annualised external funding, within the *Mutual Obligation Arrangements*, was £3,432,232 (Table 1 Row 2 in **Appendix 5**).

14.1.2 Table 2 Column G (**Appendix 5**) details 2000/01 external funding in each of the five research activity areas.

14.2 External Income (*Mutual Obligations*)

14.2.1 For 2000/01, the annualised external income, within the *Mutual Obligation Arrangements*, was £1,090,004 (Table 1 Row 3 in **Appendix 5**).

14.3 External Income (Other)

14.3.1 Annualised external non commercial funding in 2000/01 was £1,613,744 and annualised external non commercial income was £1,293,655, for projects within Row 1.g in Table 1 (**Appendix 5**).

14.4 Notes to Table 1 (**Appendix 5**)

14.4.1 For the 1999/00 R&D Annual Report, external funding (Row 3) was calculated as the sum of the grant income received in-year by the Trust and the total annualised value of multi centre research grants. External income (Row 2) was calculated as the sum of grant income received in-year by the Trust and the Trust's proportion of the total annualised value of multi centre grants.

14.4.2 For 2000/01, external funding has been calculated as the sum of the grant income received in-year by the Trust and the Trust's proportion of the total annualised value of multi centre grants. External income has been calculated as the grant income received in-year by the Trust.

15. Service Support Costs

15.1 Expenditure by Funding Categories/Management/Training

15.1.1 Table 1 (**Appendix 5**) details 2000/01 expenditure of R&D support funding in each category of externally funded research and for own account work, training and management costs.

15.2 Expenditure by Activity Areas

15.2.1 Table 2 (**Appendix 5**) details 2000/01 indicative and actual expenditure of R&D support funding in each research activity area, including primary care. Indicative R&D support expenditure for 2001/02 is also shown. Variance between planned and actual expenditure reflects continued rationalisation of R&D themes.

16. Changes in Research Activity

16.1 Indicators of Change

16.1.1 259 research projects were in progress at the end of 2000/01. Their distribution, by theme, was as follows: *Cancer* (55); *Cardiovascular Disease* (54); *Developing Fields* (41); *Physiological Studies* (51); *Respiratory Disease* (58). In cost terms, Table 2 (**Appendix 5**) shows the proportion of activity in Year 3, the degree to which it has altered, and, the nature of the replacement activity.

VI PERFORMANCE INDICATORS

17. Strategic Ability

The performance indicator, *Strategic Ability*, is covered in Part II.

18. External Funding

18.1 Sources of Funding

18.1.1 External funding within the *Mutual Obligation Arrangements*, were as follows:

Source	Funding	(%)
Research Councils	£145,860	(10%)
Universities	£ 260,326	(6%)
Charities	£1,184,868	(19%)
DH/NHSE	£ 1,561,429	(43%)
Other Government/EU	£ 279,749	(22%)
TOTAL	£3,432,232	

18.1.2 External non commercial funding, outside the *Mutual Obligation Arrangements*, was £1,613,744. (See Section 14.3.1 for additional details.)

18.1.3 In 2000/01, SMUHT was the joint recipient of £60k in funding from the DTI for the manIP consortium.

19. Publication Output

19.1 Peer-reviewed Publications

19.1.1 Details of papers/abstracts in peer-reviewed journals and books/chapter contributions, published by Trust researchers in the 2000 calendar year, are listed in **Appendix 11**.

19.1.2 There were 407 publications, distributed across the R&D themes as follows:

Theme	Number of Publications (%)
Cancer	106 (26%)
Cardiovascular Disease	71 (18%)
Developing Fields	37 (9%)
Physiological Studies	114 (28%)
Respiratory Disease	79 (19%)

19.1.3 An analysis of journal impact factors is included in **Appendix 11**. 40% of publications appeared in journals with an *ISI* impact factor >2.

20. Multidisciplinary R&D

20.1 Multidisciplinary Working

20.1.1 Whilst the majority of research undertaken in the Trust in 2000/01 was conducted by multidisciplinary teams, the proportion of projects within each theme, where a non medical practitioner took a primary role, was as follows: *Cancer* (18%); *Cardiovascular Disease* (26%); *Developing Fields* (56%); *Physiological Studies* (22%); *Respiratory Disease* (31%).

20.1.2 Examples of multidisciplinary projects, with a principal investigator from the non medical professions, were:

- dietary intake in patients with advanced cancer receiving chemotherapy;
- the use of patients' own drugs (PODs) with a self-medication option;
- investigation of the information needs of medical staff;
- exercise training for patients in chronic heart failure;
- use of personal construct psychology and repertory grid technique in people with acquired neurological communication disorder;
- clinical credibility in nursing;
- effect of white oak bark on chronic non healing wounds;
- vacuum assisted closure for a tracheostomy site;
- use of the prone position to optimise oxygenation in adult respiratory distress syndrome;
- effects of intraoperative homologous blood transfusions;
- non-surgical management of pre-tibial lacerations;
- a clinical tool to assess psychological distress in burns patients.

20.1.3 £32,390 was spent on R&D training in 2000/01 to support multidisciplinary working (Table 1 in **Appendix 5**). Details of the training are given in Section 22, including a breakdown of expenditure. An account of the support provided within the Trust to multidisciplinary research is given in Sections 8 and 22.

21. National Research Register

21.1 NRR Returns

21.1.1 The success of the SMUHT *NRR* returns in 2000/01 reflects the close working by the R&D Information Officer with researchers, South Manchester LREC and the University of Manchester RGSU to obtain the minimum dataset on all registered projects.

22. Training

22.1 Trust Research Grants for Non Medical Researchers

22.1.1 A priority for the R&D Committee in 2000/01 has been to establish annual awards in two categories – *novice researcher* and *experienced researcher* – to support non medical researchers in the Trust. £25,000 per annum for three years is being identified. Applications will be peer-reviewed and a selection panel, including external assessors, will be convened by the Director of R&D on an annual basis.

22.1.2 The purpose of the awards is to support multidisciplinary pre protocol research – either a stand-alone project or a project within a larger research programme. Successful applicants will be required to demonstrate that their research fits within Trust and national R&D priorities. Applicants within the *experienced researcher* category, additionally, will be required to demonstrate that their research is likely to contribute towards a successful collaborative funding bid to an organisation within the DoH R&D partnership arrangements (ie one of the organisations which attracts *Support for Science* funding) or to *Priorities & Needs* funding.

22.2 Postgraduate Fellowships

22.2.1 Support of non medical staff undertaking postgraduate research degrees is a key part of the capability building component of the Trust's R&D Strategy.

22.2.2 During the year, a SMUHT prosthetist was awarded an NHS R&D Training Fellowship to undertake PhD studies of the effect of torque absorbers and torque-shock absorbers on the gait of trans-tibial amputees. The Trust's *R&D Levy* is supporting £48,498 of the costs over three years. In-year costs were £3,681. This research will:

- enhance R&D capability in Prosthetics and Orthotics - its inclusion in the *Developing Fields* R&D theme denotes it as an emerging area of research;
- complement the existing peripheral vascular disease research being undertaken within the *Cardiovascular Disease* R&D theme;
- strengthen the research links between the Trust and the Faculty of Health and Social Care, University of Salford.

Another NHS R&D Training Fellowship, for a nurse researcher in the Vascular Studies Unit undertaking MPhil/PhD studies in the field of autologous transfusions in surgery, is in progress.

22.3 Higher Degrees

22.3.1 15 specialist nurses were funded through a budget held by the Directorate for Clinical and Professional Development to undertake Masters-level studies in support of the research remit of their specialist nurse role. Expenditure in 2000/01 totalled £13,577.

22.3.2 Details of higher degrees obtained by members of Trust research teams are provided in the R&D theme summaries (**Appendix 6**).

22.4 First Degrees

22.4.1 19 staff were funded through a budget held by the Directorate for Clinical and Professional Development to undertake first degrees which included a research component. Expenditure in 2000/01 totalled £11,107.

22.5 Research Skills Training

22.5.1 Research training, comprising University-based research skills modules, was coordinated through the Directorate for Clinical and Professional Development. 10 staff received funding. Expenditure on this training was £4,025.

22.6 In-house Training Programme

22.6.1 A rolling programme of monthly half-day courses on basic and advanced statistics was provided during the year to Trust researchers (medical and non medical professions and scientists from clinical support services and academic laboratories) by staff of the Department of Medical Statistics (see Section 11.4.2). The salary costs of statistical staff are included in R&D overhead costs.

22.6.2 The Head of R&D provided one-to-one tutorials for a number of research active non medical staff throughout the year. The salary costs are included in R&D overhead costs. Additional training was provided through the mentorship arrangements with the University of Salford School of Health and Social Care (see Section 7.2.11).

23. Consumer Involvement

23.1 Local Community Meeting about SMUHT Research

23.1.1 The Trust has taken a considered approach to the implementation of the R&D consumer agenda. As a first step, an evening meeting for local residents and representatives of local voluntary self-help and charitable organisations and health and social care providers (selected in consultation with the South Manchester CHC) was arranged by the R&D Directorate working with the Department of Clinical Audit. This event, which was held in September 2000 at Wythenshawe Forum, aimed to increase public awareness of the Trust's research – an essential prerequisite for successful involvement of consumer groups in R&D.

23.1.2 Over 120 attendees had the opportunity to view posters of research and clinical audit projects during an informal hospitality session which was then followed by short presentations on 10 areas of SMUHT research. These topics were suggested by the CHC as being of particular interest to the local community. The CHC arranged for counsellors to be present (although they were not called on), in recognition that some attendees might wish to discuss their clinical conditions or experiences with clinical services. The meeting was opened by the Chair of the NHSE North West Regional Office and closed by the Chairman of the Trust, signalling the importance that both organisations accorded to the event.

23.1.3 Evaluations forms completed by attendees, the presenters and the organising team are guiding the planning of the second Local Community Meeting to be held in September 2001. Following the 2000 event, South Manchester PCT asked to be a partner in the 2001 meeting and *Working for Health in Wythenshawe* has also asked to contribute to the programme.

23.2 Partnership with the Community Health Council and the NHSE North West

23.2.1 The R&D Manager, through membership of the NHSE User Advisory Group, has contributed to the development of regional strategic objectives and initiatives to address these objectives. The South Manchester CHC Consumer Lead is also a member, enabling local collaborative follow-up of this work. During the year, the R&D Administrator and R&D Information Officer participated in User Advisory Group regional workshops, held in December 2000 and March 2001, to gain a wider understanding of the consumer agenda and to learn from consumer participants.

23.3 SMUHT Consumer Representative

23.3.1 The R&D Directorate has recruited a consumer/carer to work with R&D Directorate staff and the CHC Consumer Lead to develop local responses to the consumer agenda; contribute the consumer perspective to NHSE regional events, and, provide consumer feedback from these events.

23.3.2 This SMUHT working group responded to the December 2000 regional workshop by identifying three local short-term objectives:

- explain the R&D consumer agenda to local general practitioners and enlist their support;
- raise awareness of the R&D consumer agenda amongst Trust researchers;
- explore with local self-help and voluntary organisations their role in initiatives to involve consumers in R&D.

23.4 Increasing Awareness of the R&D Consumer Agenda

23.4.1 The first objective was delivered in January 2001, in collaboration with SMPCT, the CHC and the Wythenshawe GP Clinical Tutor, through the Postgraduate Education Accredited (PGEA) Programme for local general practitioners. The team gave a number of short presentations followed by an open discussion which provided the opportunity to explore primary care perspectives on consumer issues.

23.4.2 The Director of the Consumers in NHS Research Support Unit was a keynote speaker at the *SMUHT 4th Annual Research Conference for Clinical Staff* in March 2001. This presentation was the launch of awareness-raising initiatives within the Trust.

23.4.3 A meeting of representatives of local voluntary self-help and charitable organisations, the SMUHT Patients Council and the CHC Local Health Panel is being planned to follow the Local Community Meeting in the autumn. This event will explore ways to identify and involve consumers in R&D.

23.5 Involvement of Consumers in the Research Process

23.5.1 Involvement of consumers in the research process is at an early stage, but there are many examples of good practice in the Trust:

- Urology: responsive to consumer concerns/embarassment associated with 24-hour urine collections;
- Asthma and Allergy Unit: objective assessment of coughs undertaken in direct response to consumers identifying 'cough' as the most troublesome respiratory symptom;
- Prostate Cancer: responsive to public concern about efficacy of screening in detection and prediction of prostate cancer;
- Occupational Health Research: responsive to working people's and employers' concerns about the safety of their work environments;
- Transplant Unit: examining the patient perspective of the trauma of transplant and prolonged care stay;
- Rheumatology: liaison with small groups of patients and local community residents to ascertain their priorities;
- Gastroenterology: involvement of patients with irritable bowel syndrome and their GPs in prioritising the symptoms of these disorders for investigation;
- Rehabilitation: involvement of wheelchair users in developing design modifications to address their mobility needs.

VII INTELLECTUAL PROPERTY (IP)

24. Management of IP

24.1 Management Arrangements

24.1.1 The SMUHT 1999/00 R&D Annual Report provides a comprehensive summary of the development and implementation of management arrangements for Intellectual Property. Table 3 in **Appendix 12** provides details of policy implementation.

24.2 Technology Audits

24.2.1 Innovations identified through manIP audits in the seven university and NHS partners have been grouped into five synergies/focus areas.

24.2.2 During the financial year, 11 SMUHT innovations with market potential were identified and the scope for their protection assessed. **Appendix 13** gives details of the innovations, grouped by focus areas. They demonstrate the Trust's strength in developing new devices and therapeutics to improve patient care.

- 24.2.3 Table 3 in **Appendix 12** provides details about technology audits, management of identified Intellectual Property and outputs for 2000/01. Additional details of the management of the Trust's Intellectual Property portfolio (including expenditure on assessment, protection and exploitation of identified technologies) is provided in **Appendix 13**.
- 24.2.4 One UK patent is held by SMUHT and two further patent applications have been filed by the Trust. Five patents relating to work by SMUHT employees are held by the University of Manchester and two further patent applications for technologies developed by SMUHT staff have been filed by the University.
- 24.2.5 One licence option agreement has been signed and two others are under negotiation. Eight are currently being assessed by commercial companies under confidential disclosure agreements.
- 24.2.6 In 2000/01 the Trust had £1,175 income from the commercial exploitation of technologies.
- 24.3 Evaluation of IP
- 24.3.1 The SMUHT Endowment Committee has awarded a £20,000 budget to the R&D Directorate to cover the costs of evaluating and protecting IP. These costs include:
- prior art/patent searches;
 - obtaining an independent expert assessment of the commercial potential of IP;
 - drawing up a patent specification;
 - filing a UK patent.
- 24.3.2 Expenditure to date is given in **Appendix 13**.

25. Leadership in IP Management

- 25.1 National Forum
- 25.1.1 The SMUHT IP Management Policy has been circulated, as an exemplar policy, to Trusts in the North West and elsewhere in the UK. The SMUHT *Memorandum of Understanding* with the University of Manchester has also been requested by a number of Trusts in England and Scotland.
- 25.1.2 The Trust is working closely with The Lothian University Hospitals NHS Trust (LUHT) on developing their Intellectual Property management capability. In return, LUHT is assisting SMUHT in the development of a generic commercial contract and a *Memorandum of Understanding* with the University about non commercially funded joint research.
- 25.1.3 The R&D Manager is a member of the NHSE National IP Adviser Panel. SMUHT has been selected as a model Trust for the successful development and implementation of IP management arrangements. SMUHT contributed a poster, *Learning to Manage Innovations*, to the National Health Care Innovation Meeting in December 2000.

25.2 Regional Forum

25.2.1 The R&D Manager was invited by the North West Development Agency to be one of two NHS representatives at the North West venue of the *2000 Annual Innovation Lecture*, an interactive multi centre national debate involving the UK business community and its partners in technological innovation.

VIII OUTCOMES OF RESEARCH ACTIVITY

26. Application of Research Results

26.1 Addressing R&D Priorities

26.1.1 Details about the local and national priorities addressed by the Trust's research programmes are given in Sections 5, 6, 7 and 10.

26.2 Impact on Clinical Practice

26.2.1 The R&D theme summaries for 2000/01 (**Appendix 6**) demonstrate the volume and variety of research that underpins the Trust's clinical and teaching activities and the pragmatic impact of the research on clinical service provision.

26.3 Publications

26.3.1 Details are given in **Appendix 11** and discussed in Section 19.

26.4 Partnerships

26.4.1 Details of collaborative partnerships are given in Sections 6, 7 and 10.

IX CONCLUSION

27. Change and Challenges

27.1 Reflection on Achievements

27.1.1 The further achievements of Year 3 of the *R&D Agreement* complete the Trust's agenda to transform its management arrangements for R&D. Its track record over the past three years confirms the Trust's ability to deliver high quality research, disseminate research findings, and identify and exploit Intellectual Property.

27.1.2 The new Education and Research Centre, due to open in the autumn of 2001, will serve as the hub for the Trust's research activities. The renewal of the Trust's academic profile reflects local research strengths and gives a new focus to the ongoing review and rationalisation of research programmes.

27.2 Future Challenges

27.2.1 By Year 2, the R&D Committee was already beginning to put in place a research governance framework and to engage consumers in the research continuum, so it is well placed to meet the new challenges of Year 4.

27.2.2 The new *Support for Science* and *Priorities & Needs* R&D funding arrangements will be the litmus paper test for the Trust's achievements in attracting externally funded research; strengthening its research collaborations; engaging with research programmes of the Universities of Greater Manchester, and, incorporating research findings in clinical service provision.