

REGISTERED CHARITY NUMBER: 327206

**Trustees' Report and
Audited Financial Statements for the Year Ended 31 December 2021
for
Drug Safety Research Trust**



Drug Safety Research Trust

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Drug Safety Research Trust

**Reference and Administrative Details
for the Year Ended 31 December 2021**

TRUSTEES

Professor Kenneth Ross Paterson MB ChB FRCP FFPM FBPhS (Chairman)
Professor John Camm QHP BSc MD FRCP FESC FACC FAHA FCGC CSTJ
Professor Martin Vessey CBE MD FRCP FRCOG FRCGP FFPH FMedSci FRS
Professor Allan Hunter Young MB, ChB, MPhil, PhD, FRCPC, FRCPsych
Professor Isla Mackenzie MB ChB PhD PGCertMedEd FRCP Edin FBPhS FBIHS

DIRECTOR

Professor Saad Shakir MB ChB LRCP&S FRCP FFPM FISPE MRCPG

PRINCIPAL ADDRESS

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SO31 1AA

**REGISTERED CHARITY
NUMBER**

327206

INDEPENDENT AUDITORS

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Chartered Accountants and Business Advisors
Statutory Auditor
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EN5 4BE

PROFESSIONAL ADVISERS

Solicitors
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PRINCIPAL BANKERS

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Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

The trustees present their report with the financial statements of the charity for the year ended 31 December 2021. The trustees have adopted the provisions of Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019).

OBJECTIVES AND ACTIVITIES

Objectives and aims

The Trust by way of its operational unit, the DSRU, undertakes all forms of studies and evaluations of the safety of medicines for the public benefit, including methodological research to improve existing methods including:

1. Studies to examine the safety of medicines, including new medicines, new formulations for existing medicines and when medicines are used for new indications or in new populations, or when safety issues or questions about the use, benefit-risk balance or effectiveness of medicines arise. Frequently such DSRU studies are part of risk management plans for medicines which are now statutory requirements in the EU.
2. Studies on established medicines when safety, scientific, utilisation or regulatory issues, questions, enquiries or needs for submissions arise. The issues include risk management & minimisation and methodological questions. The studies can be part of the UK and the EU regulatory requirements for risk management of medicines, though not exclusively.
3. Conducting studies to address specific safety, public health, scientific, benefit-risk balance of medicines and vaccines, utilisation and usage and regulatory issues or concerns.
4. Conducting utilisation studies for medicines and vaccines to enable understanding the use and effects of products on the healthcare system and behaviours and responses of patients and healthcare professionals.
5. Use of healthcare databases to conduct drug safety studies.
6. Establishing registries to conduct safety and utilisation studies.
7. Working with doctors to undertake studies to examine specific safety questions and medical health research networks.
8. Exploring the application of new methods such as clinical trials or database research, as well as other appropriate research methods, to understand the safety of medicines.
9. Conducting methodological research and pharmacovigilance and pharmacoepidemiology.
10. Undertaking reviews, systematic reviews, meta-analyses or benefit-risk studies to answer drug safety and drug utilisation questions.
11. Establishing research entities for studying and communicating methodological issues in pharmacovigilance and pharmacovigilance and drug safety issues
12. Lead or participate in national and international research networks and scientific collaborative projects.

We continue to monitor developments in the UK relationship with the EU and make adjustments to our systems as appropriate to address relevant issues arising from these changes. In this regard the Trust has already opened a sub-office in Dublin to maintain and develop our links with the EU following the UK's severance of membership of the EU in 2020.

The Director keeps in regular contact with the Regulatory Agencies and our European colleagues to obtain information in order to shape our strategy and policy, particularly on matters related to the impact of Brexit on medicines regulations and medical research.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

OBJECTIVES AND ACTIVITIES

Significant activities

The DSRU provides advice, education and training in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines. As one of the main providers of training and education in pharmacovigilance in Europe, its activities include:

1. Providing a range of training courses in pharmacovigilance and pharmacoepidemiology. The DSRU currently provides 17 courses per year, including academically endorsed higher education in collaboration with University of Portsmouth for Postgraduate Certificate, Diploma and a Master's degree in Pharmacovigilance and with the Faculty of Pharmaceutical Medicine for providing Pharmaceutical Medicine Specialty Training (PMST) for doctors specialising in pharmaceutical medicine.
2. Providing external training and education when required.
3. Keeping up with technological progress the DSRU intends to periodically evaluate options such as providing distance learning and other internet based educational methods.
4. Arranging national and international conferences in pharmacovigilance and pharmacoepidemiology.
5. Providing postgraduate teaching and research opportunities at all levels including MSc and PhD students.
6. Supporting postgraduate students who wish to undertake research at the DSRU
7. Providing training in pharmacovigilance and pharmacoepidemiology for pharmaceutical physicians. The DSRU has been selected by the Faculty of Pharmaceutical Medicine to provide Pharmaceutical Medicine Specialty Training (PMST) training in pharmacovigilance in the UK.
8. Supporting training and scientific communications on the safety of medicines in the UK and internationally.
9. Providing advice on matters related to the safety of medicines.
10. Producing newsletters and internet communications to general practitioners on matters to do with drug safety.
11. Providing information on drug safety which can be accessed by everyone on the DSRU website.

Routinely, reports on the results of studies are sent to the Medicines and Healthcare Products Regulatory Authority (MHRA) (an executive agency of the Department of Health) and to the European Medicines Agency (EMA) and other Regulatory Authorities in Europe to assist them in their regulatory and monitoring activities of medicines. The DSRU sends reports of its studies to Marketing Authorisation Holders of medicines and vaccines and also publishes findings of its work in scientific journals and at national and international conferences, newsletters and on its website.

Progress of the scientific work of the Unit was satisfactory throughout 2021 extending the breadth of activity to include research projects and collaborations other than Modified Prescription-Event Monitoring (MPeM). These include specialist and hospital-based studies (SCeMs), systematic reviews, registries, structured benefit-risk evaluation, drug utilisation projects and methodological research. In addition, our programme of activities has extended to include collaborating with a broad range of doctors in England through Health Research Networks from differing specialities as well as collaborating with colleagues in Europe. The policy to extend the range of scientific activities, as funding allows, will continue.

Applications for funding from grant-giving bodies, including the Department of Health Targeted Research Programme and other bodies such as the Medical Research Council (MRC), the Wellcome Trust, pharmaceutical companies and European initiatives, e.g. the European Commission, will continue as and when calls are advertised. The DSRU continues to function as one of the leading Units in the field of monitoring and studying the safety of medicines both in the UK and internationally, as well as being a leading organisation in teaching and training in these fields.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

OBJECTIVES AND ACTIVITIES

The DSRU has a long-standing partnership with the NHS Rx Services to receive prescription data that are necessary to conduct Modified Prescription-Event Monitoring studies to improve the understanding of the safety of new drugs used in the general population. This partnership has the support of the Department of Health and senior staff at NHS Rx Services.

Since application for Section 251 exemption of the NHS 2006 Act became a requirement, the Trust has applied annually to the Confidentiality Advisory Group (CAG) of the Health Research Authority for approval to use patient data without consent. Application was again made in 2021 and was successful.

The formal collaborative partnership programme agreement, required to develop the partnership with the NHS Rx Services, to supply improved prescription data is in place and we continue to maintain good communications. In the unlikely situation that the DSRU ceases to receive data for whatever reason from the NHS Rx Services, the DSRU is committed to continue its work on studying the safety of medicines by other methods and providing education and training in pharmacovigilance and drug safety.

The main objectives of the Unit for the next year are:

1. To continue the monitoring and research programme on the safety and risk management of vaccines and medicinal products for the treatment COVID-19
2. To undertake all forms of studies and evaluations of the safety and benefit-risk of medicines and vaccines alone or in collaboration with other organisations
3. To plan and support organisations to implement risk minimisation measures for medicines and vaccines
4. To use its studies to support risk management, risk minimisation and monitoring the effectiveness of risk minimisation and utilisation of medicines and vaccines
5. To conduct studies to understand drug safety issues
6. To conduct studies to understand the utilisation (use) and effects of medicines and vaccines
7. To continue its scientific work in methodological aspects of drug safety including leading or participating in national and international collaborative projects
8. To continue its activities in advice, education and training in pharmacovigilance and pharmacoepidemiology
9. To consolidate its scientific communications programme such as the DSRU international pharmacovigilance observatory to inform both the medical/scientific communities and the public about important pharmacovigilance issues
10. To continue to try to secure sufficient funding from different sources (public and private) to enable the continuation and growth of the charity's activities

Public benefit

The Trustees confirm that the Charity Commission's general guidance on public benefit has been considered in relation to the objectives of the Charity.

The objectives, activities, performance and achievement sections of this report clearly set out the activities which the charity undertakes for public benefit. The Trustees confirm that they have complied with their duty in Section 4 of the Charities Act 2006 to have due regard to public benefits guidance published by the Charities Commission in determining the activities undertaken by the Charity.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

ACHIEVEMENT AND PERFORMANCE

Charitable activities

The successful annual submission and subsequent approval and support of the Ethics and Confidentiality Committee of the Confidentiality Advisory Group (CAG) of the Health Research Authority for Section 251 exemption under the NHS Act 2006 was achieved for the twelfth year running.

The academically endorsed higher educational training in collaboration with the University of Portsmouth for Certificate, Diploma and Masters degree in Pharmacovigilance continued, with 22 students currently enrolled at the end of the year.

Eleven scientific papers were published in medical literature. Four oral and poster presentations on the results of studies were given by the Director and Research staff at national and international medical and scientific conferences. One Vaccine Active Safety Surveillance study, one Safety Profile Summary Report and six Spontaneous Data Reports were completed during 2021 as well as the provision of pharmacovigilance consultancy support to pharmaceutical companies.

Education and Professional Capability

The educational training of staff has been maintained, including continuing professional development. In addition, the DSRU has provided advice on safety of medicines issues.

Teaching & Education

The Director taught at an MSc Course at Oxford University. In addition, teaching and presenting at national and international scientific meetings continued by both the Director and senior scientific staff enabling the scientific profile of the Unit and its work in public health and drug safety to be maintained.

The DSRU and staff at the DSRU have provided training for general practitioners on effective and safe prescribing of medicines.

Training Courses for Pharmaceutical Medicine Speciality Training

The DSRU continues to deliver teaching courses in pharmacovigilance, providing training on drug safety modules of Pharmaceutical Medicine Specialty Training (PMST), for pharmaceutical physicians on behalf of the Faculty of Pharmaceutical Medicine, Royal College of Physicians. Eight students attended these modules during the year.

Partners and Stakeholders

Universities of Portsmouth

Collaborations with the University of Portsmouth on joint studentships and joint training continue.

Regulatory Agencies

Close links were maintained throughout the year with the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) with regular reports on safety issues submitted, contributing to the better understanding of the safety of a number of important medicinal products. The DSRU is a member of the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP), a project led by the European Medicines Agency and developed in collaboration with European experts in the fields of pharmacoepidemiology and pharmacovigilance. Senior staff of the DSRU regularly participate in meetings of the ENCePP network group.

VAC4EU

The DSRU is a member of VAC4EU which is a collaborative network of 46 units across Europe which conduct studies on the safety and effectiveness of vaccines. The network is led by Professor Miriam Sturkenboom (the University of Utrecht in the Netherlands). The DSRU is conducting three studies on COVID-19 vaccines in collaboration with members of VAC4EU. The DSRU is using Clinical Practice Research Datalink (CPRD), the leading resource in the UK of primary care clinical data to conduct the studies on COVID-19 vaccines by AstraZeneca, Pfizer and Moderna, while our collaborators are using databases in a number of European countries. We have been asked recently to join another multi-centre study on myocarditis and pericarditis with the Pfizer vaccine using CPRD.

Lareb

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

The DSRU is running the UK arm of the Covid Vaccine Monitor Study, a European-wide study organised by the Netherlands Pharmacovigilance Centre, Lareb. In this study a web app is used to monitor the safety of all COVID-19 vaccines amongst vaccinees in seven European countries. The aims of the study are to generate incidence rates of patient-reported ADRs for each COVID-19 vaccine brand in near real time and to describe differences in those incidence rates between different vaccine batches used across the participating countries. EU work package partners are using anonymised, aggregated data from all countries to produce a dashboard for the monitoring of side effects and signal detection.

International scientific leadership collaboration

The DSRU is leading an International Working Group (IWG) on Signal Detection and Management in Pharmacovigilance. The Group includes some of the best experts in the world in this field. The objective is to examine the impact of new developments in biomedical sciences on signal detection and management in pharmacovigilance. Such developments include artificial intelligence and machine thinking, the use of big data, the application of genetic knowledge in detecting and evaluating adverse drug reactions. The work of the IWG was interrupted for nearly two years because of the COVID-19 pandemic. The DSRU is working now to restart its activities with broader objectives which are to address new developments in pharmacovigilance and pharmacoepidemiology.

Investment performance

The Trust's strategy to invest whenever possible to offset for leaner years when donations are reduced, will be maintained. Full details of investment income and performance can be found in the notes to the financial statements.

Special investment powers of the Trustees

The Trust has undertaken investment in equities and bonds through Investec Wealth & Investment Ltd. In order to monitor the investment portfolio performance, two Trustees and the Director act as a sub-committee. This group, on behalf of the Board of Trustees, deals with all matters relating to the investment portfolio and meets with representatives of Investec Wealth & Investment Ltd at appropriate intervals. It is the policy of the Board of Trustees that no investments in the pharmaceutical, armaments or tobacco industries should be undertaken. The Trustees are satisfied that the current investment approach of the Trust is consistent with its investment needs, objectives and attitude to risk, which is to provide a balanced return on investment in the medium term with a moderate risk of capital loss.

Annually from a management perspective all other funds not immediately required from month to month for the normal running of the DSRU are routinely invested in fixed term deposit accounts to maximise return whenever possible.

FINANCIAL REVIEW

Asset cover for funds

An analysis of the assets attributable to the various funds described is set out in the notes to these financial statements. These assets are sufficient to meet the charity's obligations on a fund by fund basis.

Drug Safety Research Trust

Trustees' Report for the Year Ended 31 December 2021

FUTURE PLANS

The overall strategy remains the same. As in previous years the DSRU will endeavour to ensure the preservation of Modified Prescription-Event Monitoring (MPEM) as a leading system to monitor the safety of medicines in the UK and to enhance and develop it. The Unit will continue to conduct a broad range of studies to address safety questions, including add-on studies, such as case-control and case-series studies within our databases, pharmacoepidemiological studies using other data sources and a range of study designs, appropriate clinical trials, genetic studies, drug and vaccine utilisation studies, meta-analyses, systematic reviews, benefit-risk evaluation, other study methods to understand drugs and vaccines safety, effectiveness, use and utilisation. The DSRU will conduct methodological research to contribute to advance the science and methods of Pharmacovigilance.

These are part of the DSRU's objective to explore conducting studies with different methods, including using a range of data sources that enable it to achieve its objective to monitor and study the safety of medicines.

The DSRU will continue its recent successful expansion to conduct safety studies in secondary care as well as in primary care using appropriate and improved methods to answer the relevant safety questions. The DSRU will lead or participate in national and international collaborative projects that aim to improve the methods and advance the science of studying the safety of medicines. The DSRU will further develop its scientific communications programme such as the DSRU international pharmacovigilance observatory to inform the both the medical/scientific communities and the public about important pharmacovigilance issues. The DSRU continues to monitor IT and other developments in the NHS and elsewhere to ensure that it benefits from the opportunities provided by these developments. The Unit will further develop its methods and capabilities in evidence-based pharmacovigilance and risk management and maintain its place as a leading unit in providing advice, training and education in pharmacovigilance and drug safety.

STRUCTURE, GOVERNANCE AND MANAGEMENT

Governing document

The Trust is governed by a charitable Trust Deed established on 23 July 1986 with a Board of Trustees five in number. The Mission of the Trust remains to monitor, study and communicate the safety of medicines independent from both Government and industry. The Trust by way of its operational unit, the Drug Safety Research Unit (DSRU), undertakes all forms of studies and evaluations on the safety of medicines. The DSRU provides advice, training and education in pharmacovigilance and related subjects and works to improve the methods used to study and understand the safety of medicines.

As an independent registered medical charity, its aim is to achieve the highest possible scientific and ethical standards by putting the interests of patients first and to work with integrity and fairness with all partners.

Recruitment and appointment of new trustees

As a charity specialising in drug safety, the Trustees are identified for their expertise in areas which include drug regulation, epidemiology and medical statistics, experimental medicine and pharmacovigilance. Once appointed, the Trust ensures that any training required by the Trustees is provided to enable them to fulfil their role.

Organisational structure

The Trust employs a Director, Professor Saad Shakir, assisted by scientific, professional and administrative staff to conduct its day-to-day activities, ensuring that the charity's objectives are implemented. The Trust also retains the services of appropriate advisers and consultants depending upon the nature of the tasks required. During 2021 the average number of staff employed for the year was 28. In addition, nineteen consultants were engaged, to advise and assist with additional medical/research input, IT and data protection, PR/advertising and property planning matters.

Induction and training of new trustees

The Trustees acknowledge their responsibilities as set out on the statement of "Trustees responsibilities".

Changes to the Board of Trustees

There have been no changes during 2021.

Drug Safety Research Trust

**Trustees' Report
for the Year Ended 31 December 2021**

STRUCTURE, GOVERNANCE AND MANAGEMENT

Risk management

The Trustees have a duty to identify and review the risks to which the Charity is exposed and to ensure appropriate controls are in place to provide reasonable assurance against fraud and error.

The Trustees examine the major strategic, business and operational risks and confirm that systems are established to enable regular reports to be produced, so that necessary steps can be taken to control or lessen these risks. The variability of the funding of the Trust made it necessary to put in place processes to ensure that staff felt secure and motivated.

A Disaster Recovery Plan for the DSRU has been designed and completed. The plan is secured in off-site storage within a data safe.

Approved by order of the board of trustees on 16 Jan 2022 and signed on its behalf by:



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Professor K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust

Statement of Trustees' Responsibilities for the Year Ended 31 December 2021

The trustees are responsible for preparing the Trustees' Report and the accounts in accordance with applicable law and Financial Reporting Standards (FRS102).

The law applicable to charities in England and Wales requires the trustees to prepare Accounts for each financial year which give a true and fair view of the charity's financial activities during the year and of its financial position at the end of the year (unless the charity is entitled to prepare accounts on the alternative receipts and payments basis).

In preparing accounts giving a true and fair view, the trustees should follow best practice and:

- Select suitable accounting policies and then apply them consistently;
- State whether applicable accounting standards and statements of recommended practice have been followed, subject to any departures and explained in the accounts.
- make judgements and estimates that are reasonable and prudent;
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the charity will continue in business.

The trustees are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the charity and to enable them to ensure that the financial statements comply with the applicable law. They are also responsible for safeguarding the assets of the charity and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Opinion

We have audited the financial statements of Drug Safety Research Trust (the 'charity') for the year ended 31 December 2021 which comprise the Statement of Financial Activities, the Statement of Financial Position, the Statement of Cash Flows and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice), including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'.

In our opinion the financial statements:

- give a true and fair view of the state of the charity's affairs as at 31 December 2021 and of its incoming resources and application of resources, for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice, including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'; and
- have been prepared in accordance with the requirements of the Charities Act 2011.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We are independent of the charity in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Conclusions relating to going concern

In auditing the financial statements, we have concluded that the trustees' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the charity's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the trustees with respect to going concern are described in the relevant sections of this report.

Other information

The trustees are responsible for the other information. The other information comprises the information included in the Annual Report, other than the financial statements and our Report of the Independent Auditors thereon.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Matters on which we are required to report by exception

We have nothing to report in respect of the following matters where the Charities (Accounts and Reports) Regulations 2008 requires us to report to you if, in our opinion:

- the information given in the trustees Report is inconsistent in any material respect with the financial statements; or
- sufficient accounting records have not been kept; or
- the financial statements are not in agreement with the accounting records and returns; or
- we have not received all the information and explanations we require for our audit.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Responsibilities of trustees

As explained more fully in the Statement of Trustees' Responsibilities, the trustees are responsible for the preparation of the financial statements which give a true and fair view, and for such internal control as the trustees determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the trustees are responsible for assessing the charity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the trustees either intend to liquidate the charity or to cease operations, or have no realistic alternative but to do so.

Report of the Independent Auditors to the Trustees of Drug Safety Research Trust

Our responsibilities for the audit of the financial statements

We have been appointed as auditors under Section 144 of the Charities Act 2011 and report in accordance with the Act and relevant regulations made or having effect thereunder.

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a Report of the Independent Auditors that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

We ensured that the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations, and that they remained alert to instances of non-compliance throughout the audit.

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, was as follows:

- based on our understanding of the charity and sector, and through discussions with trustees and key management, we identified any specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the charity, including the SORP 2015, Companies Act 2006, taxation legislation and data protection, anti-bribery, employment, environmental and health and safety legislation; and
- we assessed the extent of compliance with these laws and regulations through making enquiries of management and inspecting legal correspondence.

We assessed the susceptibility of the charity's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:

- making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and
- considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries, particularly focused around the year-end, to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates in the notes to the financial statements were indicative of potential bias; and
- investigated the rationale behind significant or unusual transactions.

In response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:

- agreeing financial statement disclosures to underlying supporting documentation;
- reading the minutes of meetings of those charged with governance;
- enquiring of management as to actual and potential litigation and claims; and
- reviewing correspondence with HMRC, relevant regulators and the charity's legal advisors.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at www.frc.org.uk/auditorsresponsibilities. This description forms part of our Report of the Independent Auditors.

**Report of the Independent Auditors to the Trustees of
Drug Safety Research Trust**

Use of our report

This report is made solely to the charity's trustees, as a body, in accordance with Part 4 of the Charities (Accounts and Reports) Regulations 2008. Our audit work has been undertaken so that we might state to the charity's trustees those matters we are required to state to them in an auditors' report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the charity and the charity's trustees as a body, for our audit work, for this report, or for the opinions we have formed.



Cartwrights
Chartered Accountants and Business Advisors
Statutory Auditor
Regency House
33 Wood Street
Barnet
Hertfordshire
EN5 4BE

Date: 17/06/2022

Andrew Hill FCA (Senior Statutory Auditor) for and on behalf of Cartwrights

Drug Safety Research Trust

**Statement of Financial Activities
for the Year Ended 31 December 2021**

	Notes	Unrestricted funds £	Restricted fund £	31/12/21 Total funds £	31/12/20 Total funds £
INCOME AND ENDOWMENTS FROM					
Donations and legacies	2	3,375,220	-	3,375,220	767,131
Investment income	3	149,016	-	149,016	111,782
Other income		506,826	-	506,826	517,181
Total		4,031,062	-	4,031,062	1,396,094
EXPENDITURE ON					
Raising funds	4	21,974	-	21,974	18,748
Charitable activities	5				
Direct Charitable Expenditure		2,157,209	-	2,157,209	1,106,830
Other		596,824	18,780	615,604	509,575
Total		2,776,007	18,780	2,794,787	1,635,153
Net gains on investments		230,072	-	230,072	193,128
NET INCOME/(EXPENDITURE)		1,485,127	(18,780)	1,466,347	(45,931)
RECONCILIATION OF FUNDS					
Total funds brought forward		8,079,221	490,620	8,569,841	8,615,772
TOTAL FUNDS CARRIED FORWARD		9,564,348	471,840	10,036,188	8,569,841

The notes form part of these financial statements

Drug Safety Research Trust

Statement of Financial Position
31 December 2021

	Notes	Unrestricted funds £	Restricted fund £	31/12/21 Total funds £	31/12/20 Total funds £
FIXED ASSETS					
Tangible assets	9	22,110	471,840	493,950	518,883
Investments	10	4,224,909	-	4,224,909	3,419,044
		<u>4,247,019</u>	<u>471,840</u>	<u>4,718,859</u>	<u>3,937,927</u>
CURRENT ASSETS					
Debtors	11	344,120	-	344,120	11,491
Cash at bank		5,104,031	-	5,104,031	4,691,906
		<u>5,448,151</u>	<u>-</u>	<u>5,448,151</u>	<u>4,703,397</u>
CREDITORS					
Amounts falling due within one year	12	(130,822)	-	(130,822)	(71,483)
		<u>5,317,329</u>	<u>-</u>	<u>5,317,329</u>	<u>4,631,914</u>
NET CURRENT ASSETS					
		<u>5,317,329</u>	<u>-</u>	<u>5,317,329</u>	<u>4,631,914</u>
TOTAL ASSETS LESS CURRENT LIABILITIES					
		<u>9,564,348</u>	<u>471,840</u>	<u>10,036,188</u>	<u>8,569,841</u>
NET ASSETS					
		<u>9,564,348</u>	<u>471,840</u>	<u>10,036,188</u>	<u>8,569,841</u>
FUNDS					
	13				
Unrestricted funds				9,564,348	8,079,221
Restricted funds				471,840	490,620
				<u>10,036,188</u>	<u>8,569,841</u>
TOTAL FUNDS					
				<u>10,036,188</u>	<u>8,569,841</u>

The financial statements were approved by the Board of Trustees and authorised for issue on 16 June 2022 and were signed on its behalf by:


K R Paterson MB ChB FRCP FFPM - Trustee

Drug Safety Research Trust**Statement of Cash Flows
for the Year Ended 31 December 2021**

	Notes	31/12/21 £	31/12/20 £
Cash flows from operating activities			
Cash generated from operations	1	703,704	(219,881)
Net cash provided by/(used in) operating activities		<u>703,704</u>	<u>(219,881)</u>
Cash flows from investing activities			
Purchase of tangible fixed assets		(8,614)	(3,971)
Purchase of fixed asset investments		(575,793)	(853,669)
Sale of fixed asset investments		230,072	873,932
Interest received		13,304	32,622
Dividends received		49,452	48,125
Net cash (used in)/provided by investing activities		<u>(291,579)</u>	<u>97,039</u>
Change in cash and cash equivalents in the reporting period		<u>412,125</u>	<u>(122,842)</u>
Cash and cash equivalents at the beginning of the reporting period		<u>4,691,906</u>	<u>4,814,748</u>
Cash and cash equivalents at the end of the reporting period		<u><u>5,104,031</u></u>	<u><u>4,691,906</u></u>

The notes form part of these financial statements

Drug Safety Research Trust

**Notes to the Statement of Cash Flows
for the Year Ended 31 December 2021**

**1. RECONCILIATION OF NET INCOME/(EXPENDITURE) TO NET CASH FLOW FROM
OPERATING ACTIVITIES**

	31/12/21	31/12/20
	£	£
Net income/(expenditure) for the reporting period (as per the Statement of Financial Activities)	1,466,347	(45,931)
Adjustments for:		
Depreciation charges	33,547	43,002
Gain on investments	(460,144)	(284,693)
Interest received	(13,304)	(32,622)
Dividends received	(49,452)	(48,125)
(Increase)/decrease in debtors	(332,629)	154,843
Increase/(decrease) in creditors	59,339	(6,355)
Net cash provided by/(used in) operations	<u>703,704</u>	<u>(219,881)</u>

2. ANALYSIS OF CHANGES IN NET FUNDS

	At 1/1/21	Cash flow	At 31/12/21
	£	£	£
Net cash			
Cash at bank	4,691,906	412,125	5,104,031
	<u>4,691,906</u>	<u>412,125</u>	<u>5,104,031</u>
Total	<u>4,691,906</u>	<u>412,125</u>	<u>5,104,031</u>

The notes form part of these financial statements

Drug Safety Research Trust

Notes to the Financial Statements for the Year Ended 31 December 2021

1. ACCOUNTING POLICIES

Basis of preparing the financial statements

The financial statements of the charity, which is a public benefit entity under FRS 102, have been prepared in accordance with the Charities SORP (FRS 102) 'Accounting and Reporting by Charities: Statement of Recommended Practice applicable to charities preparing their accounts in accordance with the Financial Reporting Standard applicable in the UK and Republic of Ireland (FRS 102) (effective 1 January 2019)', Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' and the Charities Act 2011. The financial statements have been prepared under the historical cost convention, with the exception of investments which are included at market value, as modified by the revaluation of certain assets.

Income

All income is recognised in the Statement of Financial Activities once the charity has entitlement to the funds, it is probable that the income will be received and the amount can be measured reliably.

For donations to be recognised the charity will have been notified of the amounts and the settlement date in writing. If there are conditions attached to the donation and this requires a level of performance before entitlement can be obtained then income is deferred until those conditions are fully met or the fulfilment of those conditions is within the control of the charity and it is probable that they will be fulfilled.

Investment income is earned through holding assets for investment purposes such as shares. It includes dividends, interest and unrealised gains or losses on shares held. Where it is not practicable to identify investment management costs incurred within a scheme with reasonable accuracy the investment income is reported net of these costs. It is included when the amount can be measured reliably. Interest income is recognised using the effective interest method and dividend income is recognised as the charity's right to receive payment is established.

Other income represents management fees charged and donations received from the Trust's connected trading entity, DSRU Education and Research Limited. Management fees are included when charged and donations when received. Due to the connected nature of this entity, donation income is recorded within other income rather than within donations and legacy income in the Statement of Financial Activities.

Expenditure

Liabilities are recognised as expenditure as soon as there is a legal or constructive obligation committing the charity to that expenditure, it is probable that a transfer of economic benefits will be required in settlement and the amount of the obligation can be measured reliably. Expenditure is accounted for on an accruals basis and has been classified under headings that aggregate all cost related to the category. Where costs cannot be directly attributed to particular headings they have been allocated to activities on a basis consistent with the use of resources.

Raising funds

Costs of raising funds represent investment manager costs incurred in dealing with the listed investment portfolio

Charitable activities

Expenditure on charitable activities includes the direct costs of canying out and performing the studies and evaluations of medicines in order to meet the Trust's objectives and aims.

Allocation and apportionment of costs

Support costs are those that assist the work of the charity but do not directly represent charitable activities and include office costs, governance costs, administrative payroll costs. They are incurred directly in support of expenditure on the objects of the charity and include project management carried out at Headquarters. Where support costs cannot be directly attributed to particular headings they have been allocated to cost of raising funds and expenditure on charitable activities on a basis consistent with use of the resources. Premises overheads have been allocated on an insert detail basis and other overheads have been allocated on an insert detail basis..

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2021

1. ACCOUNTING POLICIES - continued

Tangible fixed assets

Depreciation is provided at the following annual rates in order to write off each asset over its estimated useful life.

Freehold property	- 2% on cost
Plant and machinery	- Straight line over 5 years
Fixtures and fittings	- Straight line over 5 years

Tangible fixed assets other than freehold land are stated at cost less depreciation. Depreciation is provided at rates calculated to write off the cost less estimated residual value of each asset over its expected useful life, as follows:

Freehold Land	Not depreciated
Freehold Building	2% Straight Line
Plant & Machinery	20% Straight Line
Fixture, Fittings & Equipment	20% Straight Line
Motor Vehicles	20% Straight Line

Taxation

The charity is exempt from tax on its charitable activities.

Fund accounting

Unrestricted funds can be used in accordance with the charitable objectives at the discretion of the trustees.

Restricted funds can only be used for particular restricted purposes within the objects of the charity. Restrictions arise when specified by the donor or when funds are raised for particular restricted purposes.

Further explanation of the nature and purpose of each fund is included in the notes to the financial statements.

Pension costs and other post-retirement benefits

The charity operates a defined contribution pension scheme. Contributions payable to the charity's pension scheme are charged to the Statement of Financial Activities in the period to which they relate.

Accumulated funds

The restricted fund represents the net book values of the freehold land and buildings at Bursledon Hall, Southampton. The fund balances are reduced by the depreciation charged on the buildings.

Unrestricted Funds

Unrestricted funds represent donations and other incoming resources receivable or generated for the objects of the charity without further specified purpose and are available as general funds.

Investments

Fixed asset investments are stated at market value.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2021**

2. DONATIONS AND LEGACIES

	Unrestricted funds £	Restricted funds £	31/12/21 Total funds £	31/12/20 Total funds £
Donations	3,375,220	-	3,375,220	767,131

3. INVESTMENT INCOME

	Unrestricted funds £	Restricted funds £	31/12/21 Total funds £	31/12/20 Total funds £
Gain on disposal of investment	86,260	-	86,260	31,035
Listed income	49,452	-	49,452	48,125
Interest received	13,304	-	13,304	32,622
	<u>149,016</u>	<u>-</u>	<u>149,016</u>	<u>111,782</u>

4. RAISING FUNDS

Investment management costs

	Unrestricted funds £	Restricted funds £	31/12/21 Total funds £	31/12/20 Total funds £
Fund manager costs	21,974	-	21,974	18,748

5. CHARITABLE ACTIVITIES COSTS

	Direct Costs £
Direct Charitable Expenditure	
	<u>2,157,209</u>

6. SUPPORT COSTS

	Governance costs £
Other resources expended	<u>615,604</u>

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2021

6. SUPPORT COSTS - continued

Support costs, included in the above, are as follows:

	31/12/21	31/12/20
	Other resources expended £	Total activities £
Wages	167,080	147,110
Social security	134,680	102,211
Pensions	62,210	48,358
Auditors' remuneration	11,368	10,723
Rates and water	10,598	10,659
Insurance	17,634	16,432
Light and heat	16,242	14,383
Telephone and fax	17,409	6,264
PPS	11,251	933
Sundries	2,880	4,117
Repairs and maintenance	12,085	13,565
Staff training	8,660	169
Staff medical costs	10,140	9,716
Motor and travel expenses	5,837	8,174
Trustees expenses	-	34
Computer costs	12,715	12,955
Subscriptions	30,260	35,115
Bank charges	1,365	952
Marketing costs	47,063	22,320
Equipment hire	2,580	2,383
Depreciation of tangible fixed assets	33,547	43,002
	<u>615,604</u>	<u>509,575</u>

7. TRUSTEES' REMUNERATION AND BENEFITS

There were no trustees' remuneration or other benefits for the year ended 31 December 2021 nor for the year ended 31 December 2020.

Trustees' expenses

Travelling expenses amounting to £0 (2020 - £34) were reimbursed to the trustees for attending meetings.

Trustees indemnity insurance payable during the year amounted to £6,858 (2020: £6,653).

8. STAFF COSTS

The average number of employees during the year was 30 (2020 - 24).

The number of employees whose annual emoluments were £60,000 or more were:

	2021	2020
£300,001 - £310,000	-	-
£220,001 - £230,000	1	1
£60,001 - £70,000	1	1

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2021**

9. TANGIBLE FIXED ASSETS

	Freehold property £	Plant and machinery £	Fixtures and fittings £	Computer System £	Totals £
COST					
At 1 January 2021	941,000	161,910	64,784	57,036	1,224,730
Additions	-	7,030	1,584	-	8,614
At 31 December 2021	<u>941,000</u>	<u>168,940</u>	<u>66,368</u>	<u>57,036</u>	<u>1,233,344</u>
DEPRECIATION					
At 1 January 2021	450,380	144,204	55,788	55,475	705,847
Charge for year	18,780	9,199	4,007	1,561	33,547
At 31 December 2021	<u>469,160</u>	<u>153,403</u>	<u>59,795</u>	<u>57,036</u>	<u>739,394</u>
NET BOOK VALUE					
At 31 December 2021	<u>471,840</u>	<u>15,537</u>	<u>6,573</u>	<u>-</u>	<u>493,950</u>
At 31 December 2020	<u>490,620</u>	<u>17,706</u>	<u>8,996</u>	<u>1,561</u>	<u>518,883</u>

The freehold property was last revalued on 20 December 1999 by Messrs Daniells Harison, Chartered Surveyors, on the basis of open market value for current use. The freehold land and buildings valuation has not been updated since 1999. Under the transitional relief provisions under FRS 102, this value has been treated as the deemed cost in these financial statements. The estimated market value as at the balance sheet date is in excess of £4 million.

Comparable historical cost for the land and buildings included at valuation:

	2021 £	2020 £
Cost	1,487,614	1,487,614
Accumulated Depreciation	<u>469,160</u>	<u>450,380</u>
At year end	<u>1,037,234</u>	<u>1,037,234</u>

All other tangible fixed assets are stated at historical cost.

10. FIXED ASSET INVESTMENTS

	Listed investments £
MARKET VALUE	
At 1 January 2021	3,419,044
Additions	575,793
Revaluations	230,072
At 31 December 2021	<u>4,224,909</u>
NET BOOK VALUE	
At 31 December 2021	<u>4,224,909</u>
At 31 December 2020	<u>3,419,044</u>

There were no investment assets outside the UK.

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2021**

10. FIXED ASSET INVESTMENTS - continued

Cost or valuation at 31 December 2021 is represented by:

Valuation in 2021	Listed investments £
	4,224,909

Net acquisitions at cost represent investment income reinvested at source in the relevant funds held.

11. DEBTORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/21	31/12/20
	£	£
Trade debtors	312,686	-
Prepayments and accrued income	31,434	11,491
	<u>344,120</u>	<u>11,491</u>

12. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31/12/21	31/12/20
	£	£
Trade creditors	23,881	-
Taxation and social security	75,968	41,533
Other creditors	30,973	29,950
	<u>130,822</u>	<u>71,483</u>

13. MOVEMENT IN FUNDS

	At 1/1/21	Net movement in funds	At 31/12/21
	£	£	£
Unrestricted funds			
Unrestricted Fund	8,079,221	1,485,127	9,564,348
Restricted funds			
Restricted Fund	490,620	(18,780)	471,840
TOTAL FUNDS	<u>8,569,841</u>	<u>1,466,347</u>	<u>10,036,188</u>

Drug Safety Research Trust

**Notes to the Financial Statements - continued
for the Year Ended 31 December 2021**

13. MOVEMENT IN FUNDS - continued

Net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	4,031,062	(2,776,007)	230,072	1,485,127
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
TOTAL FUNDS	<u>4,031,062</u>	<u>(2,794,787)</u>	<u>230,072</u>	<u>1,466,347</u>

Comparatives for movement in funds

	At 1/1/20 £	Net movement in funds £	At 31/12/20 £
Unrestricted funds			
Unrestricted Fund	8,106,372	(27,151)	8,079,221
Restricted funds			
Restricted Fund	509,400	(18,780)	490,620
TOTAL FUNDS	<u>8,615,772</u>	<u>(45,931)</u>	<u>8,569,841</u>

Comparative net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	1,396,094	(1,616,373)	193,128	(27,151)
Restricted funds				
Restricted Fund	-	(18,780)	-	(18,780)
TOTAL FUNDS	<u>1,396,094</u>	<u>(1,635,153)</u>	<u>193,128</u>	<u>(45,931)</u>

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2021

13. MOVEMENT IN FUNDS - continued

A current year 12 months and prior year 12 months combined position is as follows:

	At 1/1/20 £	Net movement in funds £	At 31/12/21 £
Unrestricted funds			
Unrestricted Fund	8,106,372	1,457,976	9,564,348
Restricted funds			
Restricted Fund	509,400	(37,560)	471,840
TOTAL FUNDS	<u>8,615,772</u>	<u>1,420,416</u>	<u>10,036,188</u>

A current year 12 months and prior year 12 months combined net movement in funds, included in the above are as follows:

	Incoming resources £	Resources expended £	Gains and losses £	Movement in funds £
Unrestricted funds				
Unrestricted Fund	5,427,156	(4,392,380)	423,200	1,457,976
Restricted funds				
Restricted Fund	-	(37,560)	-	(37,560)
TOTAL FUNDS	<u>5,427,156</u>	<u>(4,429,940)</u>	<u>423,200</u>	<u>1,420,416</u>

14. EMPLOYEE BENEFIT OBLIGATIONS

The company operates a defined contribution pension scheme. The assets of the scheme are held separately from those of the company in an independently administered fund. The pension cost charge represents contributions payable by the company to the fund. These amounted to £62,210 (2020 - £48,358). Contributions totalling £14,119 (2020 - £7,991) were payable to the fund at the year end and are included in creditors.

Drug Safety Research Trust

Notes to the Financial Statements - continued for the Year Ended 31 December 2021

15. RELATED PARTY DISCLOSURES

Other income includes the following income received from DSRU Education and Research Trust, a company limited by guarantee, which is controlled by the Charity and in which Professor Saad Shakir is sole company director. During the year:

Management fees totalling £78,000 (2020: £78,000) were charged to the company for use of shared premises and administrative resources;

Salary recharges totalling £33,276 (2020: 32,017) were made to the company for the use of shared staff; and

A donation of £395,550 (2020: £407,164) was received from the company. The value of the donation each year is determined such that the company reduces its profits chargeable to tax to £nil each year.

Drug Safety Research Trust**Detailed Statement of Financial Activities
for the Year Ended 31 December 2021**

	31/12/21	31/12/20
	£	£
INCOME AND ENDOWMENTS		
Donations and legacies		
Donations	3,375,220	767,131
Investment income		
Gain on disposal of investment	86,260	31,035
Listed income	49,452	48,125
Interest received	13,304	32,622
	<u>149,016</u>	<u>111,782</u>
Other income		
Other income	506,826	517,181
	<u>4,031,062</u>	<u>1,396,094</u>
EXPENDITURE		
Investment management costs		
Fund manager costs	21,974	18,748
Charitable activities		
Wages - direct	1,059,361	777,162
General Practitioner costs	149,555	(200)
Other direct costs	948,293	329,868
	<u>2,157,209</u>	<u>1,106,830</u>
Support costs		
Governance costs		
Wages	167,080	147,110
Social security	134,680	102,211
Pensions	62,210	48,358
Auditors' remuneration	11,368	10,723
Rates and water	10,598	10,659
Insurance	17,634	16,432
Light and heat	16,242	14,383
Telephone and fax	17,409	6,264
PPS	11,251	933
Sundries	2,880	4,117
Repairs and maintenance	12,085	13,565
Staff training	8,660	169
Staff medical costs	10,140	9,716
Motor and travel expenses	5,837	8,174
Trustees expenses	-	34
Computer costs	12,715	12,955
Subscriptions	30,260	35,115
Carried forward	531,049	440,918

This page does not form part of the statutory financial statements

Drug Safety Research Trust**Detailed Statement of Financial Activities
for the Year Ended 31 December 2021**

	31/12/21	31/12/20
	£	£
Governance costs		
Brought forward	531,049	440,918
Bank charges	1,365	952
Marketing costs	47,063	22,320
Equipment hire	2,580	2,383
Depreciation of tangible fixed assets	33,547	43,002
	<u>615,604</u>	<u>509,575</u>
Total resources expended	<u>2,794,787</u>	<u>1,635,153</u>
Net income/(expenditure) before gains and losses	1,236,275	(239,059)
Net losses on investments		
Net gains / losses on investments	<u>230,072</u>	<u>193,128</u>
Net income/(expenditure)	<u><u>1,466,347</u></u>	<u><u>(45,931)</u></u>

This page does not form part of the statutory financial statements

