PSI/RSS Joint Assessment Committee

Union proposal

Introduction

This is a report from the Joint Assessment Committee appointed by the PSI Board of Directors and the RSS Council to look at the desirability of possible union between the two organisations, and how this might practically be achieved. Annex 3 contains a list of members of this Joint Assessment Committee. This report to the governing body of the two organisations makes the recommendation that the PSI and the RSS come together as a single influential body, mainly run through the creation of a new Pharmaceutical Statistics Section (PSS) of the Royal Statistical Society.

The opportunity

The opportunities are great. This union would create a stronger more unified voice for statistics and would expand the connections between statisticians across industry and academia. Drug development continues to evolve and change with regard to methodologies and new data sources.

The link to the RSS could help facilitate this and ensure that PSI (as a section) is seen as leading in innovative thinking. A merger would make it easier for PSI to achieve many of its long-term strategic objectives. PSI members would benefit from being part of a bigger organisation that is capable of making investments in IT, staffing and services that are difficult for a smaller organisation. They would benefit from the existing infrastructure of the RSS, including a physical building, a team of specialist staff rather than a generalist management company, a strong web and digital team.

The RSS would also benefit from such an arrangement through having a new committed set of volunteers join the Society, and with the new Pharmaceutical Section being a role model for other sections in the amount and range of its activity. Over time we would expect economies of scale and so the two bodies should be able to achieve more and have a greater influence together than each of them can do apart.

Risks and Mitigation

There are always risks. PSI members will feel most vulnerable that their organisation will be swallowed up by the RSS. We are confident that a charter for the PSS (an example of which is shown in Annex 2) that details objectives, activities, support and governance will maintain the best of the character and services of PSI within the RSS. Documenting this outline agreement at an early stage of negotiations makes clear the desire of the RSS to preserve the energy of PSI volunteers and we recommend that PSI have a roadshow to take this proposal out to their members, and that they are accompanied by RSS representatives who

can be questioned by PSI members. From the RSS side the main risk is around how best to integrate and operationalise supporting PSI and to ensure efficiencies of scale. In order to manage risks, we propose a number of safeguards. First, we recommend taking time over transition. Secondly, we suggest a review point within four years where both bodies can check the union is operating as anticipated and both bodies wish to continue with the agreement. Up until this point we suggest an 'asset lock' which means that PSI reserves are safeguarded and can be taken back by PSI if it is decided the arrangement is not working.

There are always risks and transition costs which come with change, but in the long term we believe that the needs of the statistical community will be best met by PSI and the RSS coming together as a single influential body.

This report was commissioned by the PSI Board and RSS Council, but will no doubt be of interest to members of both organisations. In order to deliver a report that is manageable, we have not sought to explain all details about how the two organisations currently work (although many have been examined). However we recognise there will be particular interest from PSI members as to how the RSS works in practice. Therefore we recommend that if PSI and RSS do decide to pursue this path, more information is made available to both sets of members about what the two organisations do and what union would mean in practice.

Discussions so far

The Joint Assessment Committee was set up with appointments from both the RSS and PSI and met three times. Our terms of reference were:

To explore the benefits and risks of a potential merger of PSI into the RSS for the work of both organisations. To develop proposals which would assess how the move could benefit both societies and their respective memberships and how the administration and structure of the resulting organisation would preserve the focus of PSI within the broader network of the RSS. To look at each activity of PSI and to consider how it could feasibly be taken forward within the RSS. To produce a proposal for the PSI Board of Directors and the RSS Council which they would then independently consider as to whether it was in the best interests of their organisation. Alternatively, to state if the committee takes the view that there is no structure which would be of benefit to both organisations. Individual committee members would be representing the organisation that nominates them (noting that some may be jointly nominated by both organisations) but would seek to develop a proposal that is in the interests of both organisations where that is possible.

The case for union

The RSS and PSI have similar aims and objectives and could be more influential together. We have mapped the activities of the two organisations and there is considerable fit. More detail on this is available in Annex 1.

Advantages for PSI

Community and voice

- Being part of the wider community that the RSS opens up, including keeping up with developments in statistical methodology; open data; data science etc.
- Having a stronger, more influential voice. The RSS has proven ability in recent years to have political influence (e.g. giving verbal evidence to the Science and Technology committee on big data) and media coverage in national press (e.g. recent statement

on the tragic French clinical trials picked up by Nature and elsewhere) and this could be used to give more coverage to PSI's issues such as lobbying against cuts in MSc funding which is a recent issue due to MRC cutbacks.

- Links to the RSS local groups network, allowing PSI to hold regional events in partnership with a network of local statisticians.

Benefits to members and shared resources

- New benefits to PSI members including Significance magazine, RSS e-bulletin with updates on news for the sector; discounts on a wide range of events; RSS member discounts on wine, gym memberships, insurance etc.
- Access to the RSS building as a venue in central London for the use of individual members or for scientific meetings
- PSI members would have the ability to apply for chartered status which shows formal recognition of statistical qualifications, professional training and experience.
- Ability of PSI members to contribute to a wider range of initiatives through the RSS – e.g. Statisticians for Society (pro bono work); RSS 2015 General Election campaign to make MPs more statistically literate.
- Use of the specialist skills of the RSS staff. The RSS has staff members who are specialists in their areas e.g. training; IT, web and digital; press and policy; events organisation; membership recruitment; finance with an executive director's office that works with the senior officers to set the strategy of the RSS. This would allow more professional delivery than may be possible through a generalist management company.
- The PSI Board of Directors would be able to provide better services to members as there would be less time spent on administration of PSI and more time to concentrate on the scientific issues and services that have added value to the membership.

Investment and safe-guarding the organisation

- Ability to invest in longer term infrastructure – e.g. IT, online training, membership database. For PSI to invest further in its infrastructure it would likely have to put up membership fees. For instance the RSS is currently investing in a Moodle platform to deliver online training and this is something that PSI is not in a position to do.
- Financial strength. The RSS has a strong business model with diverse income streams (journals, membership, training, venue hire, conference, sponsorship, grants) and solid financial reserves. In particular it is developing its commercial income streams. PSI would benefit from being part of a financially stronger organisation.
- Long term safeguarding of the organisation. In a world where all membership organisations are finding it harder to recruit and retain members, PSI's long term future is stronger as part of a bigger organisation.
- International benefits: The growing RSS online presence helps to expand its reach internationally. For example in 2015, 40% of traffic to the RSS main website and 53% of traffic to the Statslife website, was from outside of the UK. For the RSS YouTube channel, 80% of the watchtime was from overseas.

Benefits to the RSS:

- PSI is recognised as a proactive and dynamic organisation which has strong links to industry and regulators as well as playing a role in furthering drug development thinking and good statistical practice.
- It would give increased membership, reach and depth to the RSS and strengthen its voice.
- Expanding the network of statisticians to which its members have access; just as practicing statisticians benefit from access to methodologists and developments in methodology, methodologists benefit from access to practicing statistician's knowledge of the context in which novel methods must be applied
- There is a potential to bring new, active volunteers to the RSS. PSI has a dynamic culture and this could inspire other sections in the RSS to do things in new ways which they had not previously considered.
- New sponsorship opportunities and contacts.
- The pharmaceutical community is very active internationally and it would help the RSS expand its international reach.

Addressing key concerns:

During discussions there were a number of key concerns from the PSI side which are worth mentioning upfront, including the retention of the PSI brand, PSI conference and the PSI journal.

- The PSI brand has some goodwill attached to it (particularly at European level, and through its conference). In our view a key aim should be to build or transfer that goodwill to the RSS brand over time. We would suggest committing to seeking professional advice on how to best manage multiple sub-brands and following through on the advice to leverage the best of both brands.
- In terms of PSI conference we recognise that this is a PSI flagship event and suggest it should continue in its present form. We recognise that the RSS has a strategy to make its annual conference a broad event, but we believe that this would not be threatened through also having a specialist pharmaceutical conference.
- We recommend the maintenance of the journal Pharmaceutical Statistics. although the arrangements with the publishers are complicated and will require negotiations between the societies and the publishers. (This is addressed in more detail in the due diligence appendix).
- Ability to act at European level. PSI currently is a major player in the EFSPI European network. Joining the RSS would not in any way restrict the PSI's ability to operate in this space.

How it would work:

In this short report we outline how we see key areas being taken forward if union were to happen. At this stage we are outlining what we see as the direction of travel. If the proposal were pursued then more detailed transition planning would be required. We have developed a draft Memorandum of Understanding (annex 2) which would give the foundations for a union.

We would propose that PSI would become the Pharmaceutical Section within the RSS. The RSS has a dozen well established sections which have a degree of autonomy within the

Society. PSI would be the largest and most active section as other sections do not have their own annual conferences run over a number of days and so many ongoing activities. Sections are largely run by their committees, the members of which are elected annually at a section AGM. Sections can have sub-groups. Although sections have traditionally been groups which almost solely organise meetings, they are becoming more active in other areas such as policy development and a way to engage the membership with the wider Society. Most of the current PSI activity would continue to run through the section, sometimes in partnership with other parts of the RSS.

There is an active Medical Section of the RSS and there is no intention to combine PSS with the Medical Section, although collaboration between the two sections would be encouraged and there would be a representative on both sections.

Transitional arrangements/timeline: If a union goes ahead it would be important to have enough time to have a smooth transition. If approval is given by both the RSS Council in March and a PSI AGM in autumn 2016 then there would be approximately 3 months left of the PSI management contract with MCI. MCI has indicated it is happy to move to a 12 month rolling contract, and so we would recommend extending this for 1 year until the end of 2017 so that the RSS could have a thorough handover from MCI and work to embed the PSI work streams into the RSS activities. There would likely need to be some recruiting of staff and reorganising of roles as staff took on more activity and there would need to be adequate time to put this into place.

We would recommend that PSI members are given free RSS membership mid-way through 2017. Members would have six months of RSS services to have a taste of the organisation and activities and then be able to renew at the end of 2017 if they are happy. There will be members of both organisations who will pay for both memberships for a year and it will not be possible to give a discount. However, these people will save money in the long run as they will only pay for one membership in the future.

Finances and reversibility: We recommend that there is a review point within four years. At that stage we think there should be an ability to exit if the arrangement is not working. We recommend that PSI's reserves (circa £130k at present) are earmarked, and should PSI exit again after the review point, they are able to take their reserves back with them. After the review point, however, assuming both parties are happy to continue, we would then expect the reserves to be de-designated and just part of the overall RSS reserves, as the two organisations would be fully integrated. It is worth being clear that if PSI chose to leave the RSS at the review point, then members would be free to choose whether or not they were going to re-join PSI and/or stay within the RSS. There would be no such thing as 'PSI members within the RSS'.

Due Diligence

Operations

A key question for the RSS to think through is how to resource the new Pharmaceutical Section. It would be through some combination of existing staff, new staff and outsourced consultants. For example, PSI conference could continue to be run by an events management company.

Governance: A PSI merger would not change the overall governance of the RSS in terms of its Council/trustees. When recruiting Council members the RSS tries to have a range of people over the breadth of statistics and this includes pharmaceutical statisticians. We would recommend that for the first four years after merger there is a PSI representative who is a member of the RSS Council and Executive Committee to ensure merger issues are represented at the highest levels.

Member profile: Roughly 25% of the contacts in the PSI database overlap with RSS fellows. Some of these are web and affiliate members but this signifies strong ties between both organisations. However there would be a potential for the RSS to gain around 400-500 members. We recognise that at £132 RSS membership fees are higher than PSI fees, although the majority of PSI members have their fees paid by their employer.

If there is a merger members of PSI would transition into the category of 'fellow' (at a fee of £132) although most of the members would be qualified for professional membership (at a fee of £184 for CStat). Therefore we recommend that the RSS Professional Affairs Committee consider developing a process to 'fast-track' applications to allow PSI members to become professionally qualified as soon as possible. Marketing professional membership to PSI members would be helped by such a fast-track process. There could be a special mentoring programme set up for pharmaceutical statisticians' to help the new Gradstat's transfer smoothly into the Society and value their membership.

Culture: Although both the RSS and PSI have similar aims, there is a difference in culture between the two organisations that needs to be recognised and adjusted as they merge closer together. PSI is a membership organisation whose members join because of the services it provides. The RSS is a charity and although its members do receive direct benefits this is not its primary purpose. The RSS is working towards demonstrating its charitable aims as a member benefit in itself as well as improving the member experience. For example, a member discounts package with discounts on travel, car hire and other services has recently been introduced and is promoted to members.

There is also a difference in size of the organisations. PSI is smaller and has no staff so there is a perceived ability that things happen quickly. The RSS is larger and has around 25 staff. In a transition it would be important for PSI volunteers to understand the different processes at the RSS (i.e. booking meetings, updating the website, making new investments or changes in policy). Time and effort would have to be put in to look at processes and how they might be explained and adapted if needed.

Admin/Database: It is helpful that PSI and RSS both use the iMIS platform, so merging databases should be relatively straight forward although there are bound to be different user definable fields. However there will be some costs for consulting time to do this, or for a

temp to put the information into the RSS database. PSI would need to get the permission of its members to be contacted by the RSS before a merger.

Events and one day meetings: The PSI events (except for conference- below) should be able to merge into the Society's schedule of activities relatively easily. There may need to be some additional staff resource to cover this area.

One-off training courses: The RSS could integrate the PSI training programme into its own training programme which it is working to expand. There would be an increased opportunity to expand reach as both societies are looking to expand into online training. If some courses were held at Errol Street there would be increased profit margins in not having to pay for a venue. The Society is implementing a more consistent fee structure to allow for easy on-line payment so there may need to be some adjustment to fees but the fees are market rate and should not be much different than PSI members are used to paying.

Intro-to-industry course: These outreach courses which are volunteer led would to continue within the RSS and could be a useful recruitment tool.

Webinars: This is an area where the RSS is looking to expand and bringing in PSI activity into the fold would help grow this activity. The Society and PSI are both looking at putting more content into the member's area or behind a paywall and increased content from PSI would help the RSS in this arena. The larger scale of the RSS operations could help PSI put its content online.

Publications and Communications:

Journal: We recommend that there is a commitment to keep a pharmaceutical journal with an editorial board comprised of people from the pharmaceutical community. This is a complicated area given that in the PSI contract with Wiley, Wiley owns the PSI journal in a way that is very different to the RSS contract. The RSS is currently re-tendering its contract for its publications and if it did decide to move away from Wiley it would be important to ensure the new publishing contract allowed for the continuation of the PSI journal without contravening any non compete clause. Due to the timing of the RSS journal tendering process and the PSI contract with Wiley,a decision on the journal will need to be taken by the end of 2016.

Quarterly online member's magazine: It is likely that in a merger the 'SPIN' magazine would be wound-up to be replaced with more electronic communications. In the coming period the RSS will be working on making its individual communications more tailored and letting people choose the type of content they are interested in and hopefully this would be sufficient to replace this communication. The RSS found that members were satisfied when RSS News was replaced with electronic communication and the members recognised the cost involved and that they could be more engaged through electronic means. There would potentially be some additional staff resource involved to make this communication work properly. The volunteer energy which has been involved in 'SPIN' would need to be harnessed and could be a good resource in helping to create content for the new e-newsletters.

Fortnightly email: The RSS and PSI both send out a fortnightly email to members. The RSS is looking to make this more tailored and hopefully this would be well received by all members. The volunteer resource that is put into the current PSI email could be harnessed to create content for the new email.

Website: In the long term we recommend that the PSI website would be closed with the content from the site integrating within the RSS website, keeping the depth and specialist content of the site. However this should happen after showing where key material would move across. Currently the PSI site is doing several things – it is a repository for meetings, an outward window etc. Planning should be developed for where different things should migrate – e.g. meetings archives could be replaced with e.g. the basecamp software that the RSS currently uses. Since a website can be considered to be a key part of branding for an organisation, negotiations should focus on the timetable for this migration.

***Outreach/Careers**:*

PSI careers event: The section would continue this activity.

Careers materials: PSI activities in this area could help expand RSS outreach efforts.

Student outreach: The PSI work in this area is not dissimilar to RSS activities and should be able to continue.

University prizes: This costs relatively little and could be an opportunity to help keep contact with Universities so it should be able to continue within the RSS. The RSS operates a similar programme where each University which has an accredited degree is able to nominate one student (or two if they have both B.S. and MSc courses) free membership (GradStat) for a graduate.

Regulatory Review and Debate: The EFSPI/PSI regulatory committee provides the industrial statistical viewpoint on regulatory issues. The regulatory committee form expert group and working groups to address regulatory statistical issues. Most of this work is joint work with PSI/EFSPI with PSI being the major contributor to EFSPI. There is a limited potential for potential policy clashes. However the RSS is a diverse body and there are areas where certain segments will have different policy views. In the event of conflict these issues will need to be discussed and resolved in a timely fashion.

Industry outreach:

Before the headlines: As this activity is in conjunction with the RSS already this should be easy to maintain while keeping PSI volunteers involved.

Pharma stats award: As this is a joint PSI/RSS award this should be easy to continue in its current form.

Memberships:

Membership of EFSPI: Engagement with the European federation of pharma stats body is clearly an important part of PSI work that would need to be maintained. The RSS should commit to this. EFSPI has other member bodies that are subgroups, and so it should not be a barrier for PSI to continue to be active.

Scientific working groups: These working groups would be maintained as they are a way of harnessing volunteers who are interested in specific topics and because they are co-sponsored with EFSPI. There would need to be more work to consider how the PSS and RSS keep track of the multiple working groups within the volunteer structure.

Draft Memorandum of Understanding between the RSS and PSI on the creation of a pharmaceutical statistics section

Objectives

The objectives of the Pharmaceutical Statistics Section of the Royal Statistical Society are:

- For statistics to be used effectively in drug discovery, development and regulatory science so that regulations, decision making and treatments are informed by evidence
- for a strong body of professional statisticians to maintain and develop the skills, networks and standards they need to critically apply methodology, interpret results and communicate findings in the pharmaceutical industry
- to create and sponsor forums where statistical topics relevant to the pharmaceutical industry are discussed, innovation can be championed and relevant methodology can be advanced, applied and made accessible
- To promote statistics and statistical programming as a profession of choice
- To contribute to the outreach and statistical literacy work of the Society

Activities

The pharmaceutical section will

- organise at least one conference, three scientific meetings, three webinars, a careers event and four training courses (including an introduction-to-industry course) each year aimed at statisticians working in the biopharmaceutical industry
- contribute to and lead European debate on pharmaceutical statistics through RSS membership of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI)
- Promote best practise, review regulatory policy and guidelines, drive debate on future guidance, and engage with statisticians in European regulatory agencies relevant to the application of statistics in the biopharmaceutical industry
- Provide recommendations for the editorial board of the joint organisation's journal of pharmaceutical statistics
- Co-ordinate activities with other sections to promote the objectives of the RSS

Composition

The PSS's committee will

- Consist of a chair, vice-chair, meetings secretary, each of whom will be elected by the members of the RSS
- Consist additionally of up to ten further representatives of its sub-committees/scientific working groups, each of whom will be nominated onto the committee by the chair
- Sub-committee/working-group membership will be determined by the sub-committee/working group chair.

Governance and finance

- The chair of the pharmaceutical section will serve as member of the RSS council for a four year period
- The chair will also be co-opted onto the RSS executive committee for a four year period
- The section committee will produce an annual report detailing its activities and income/expenditure
- The section would receive a budget on an annual basis to achieve its activities and the budget would be contingent on its ability to generate revenue in line with agreed targets
- The section will communicate with the Medical Section and would have a representative serving on both committees.
- PSI needs to define the mechanism by which any decision to exit would be recognised as a legitimate and authoritative and binding decision

Delegated authority

- The chair of the pharmaceutical section can, or can nominate representatives to speak on behalf of the members of the pharmaceutical section of the Royal Statistical Society in pharmaceutical industry working groups, to pharmaceutical companies, to agencies regulating the pharmaceutical industry (e.g. MHRA, FDA, EMA) and in the scientific literature.
- Where matters of policy are contentious or there is a potential clash with positions from some other part of the RSS these should be escalated to the Executive Director and President for guidance.
- The pharmaceutical section's committee's responsibilities may be delegated to its sub-committees and to its scientific working groups

Communications and branding

- Members of the RSS will be able to register as members of the pharmaceutical section, and will receive member communications targeted to this section
- The PSI website will transition to rss.org.uk, and the PSI style-sheet (including logo) will transition to RSS house style over four years
- Brand guidelines would be established following professional advice with the aim of bringing the goodwill within the PSI brand across to the RSS brand over time.
- The PSI brand will be used only in areas of PSI's work and would not extend beyond related activity.

Annex 3

Membership of the Joint Assessment Committee

Name	**Nominated by**
Robert Cuffe	PSI
Mark Morris	PSI
Naomi Givens	PSI
Nigel Howitt	PSI
Katherine Hutchinson	PSI
Steve Pyke	PSI and RSS
Andy Grieve	PSI and RSS
Deborah Ashby	RSS
Sue Todd	RSS
Rob Mastrodomenico	RSS
Jen Rogers	RSS

with support from RSS staff members Hetan Shah and Sarah Simpson